Exhibit 161

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX

Response to the November 2005 National Stone, Sand & Gravel Association Report Prepared by the R.J. Lee Group, Inc "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project"

April 20, 2006

United States Environmental Protection Agency Region 9
Response to the November 2005 National Stone, Sand & Gravel Association report prepared by the R.J. Lee Group, Inc:
"Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project"

This document constitutes the United States Environmental Protection Agency Region 9 (EPA Region 9) response to the major findings and conclusions of the National Stone, Sand & Gravel Association report "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project" prepared by the R. J. Lee Group (R. J. Lee Report). A more detailed analysis will be completed after additional information is received from the R. J. Lee Group and the National Stone, Sand & Gravel Association,[1] and the United States Geological Survey (USGS).

The R. J. Lee Report draws conclusions that are contradicted by the El Dorado Hills data and by generally accepted scientific principles for measuring asbestos exposure.

Overview

The R. J. Lee Group review of the EPA data was contracted by the National Stone, Sand & Gravel Association. The El Dorado County Office of Education funded the three reviewers who wrote letters in support of the R. J. Lee Report and whose reviews are included in this response.

The EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment was designed to measure the exposures to asbestos fibers, if any, that resulted from sports and play activities that disturbed dust and soil. EPA Region 9 adhered to accepted EPA standards for sampling and analysis, including rigorous quality assurance/quality control, and to the standard methodologies of EPA exposure and risk assessment.

The R. J. Lee Report Criticizes EPA Region 9 for Using Established Scientific and Public Health Protocols - In assessing naturally occurring asbestos exposures in El Dorado Hills, EPA evaluated asbestos exposures using the PCME (phase contrast microscopy equivalent) asbestos fiber size classification. The PCME classification was used because human epidemiological studies, which form the basis of knowledge of asbestos health effects, measured asbestos fiber concentrations using phase contrast microscopy (PCM) analytical methods. PCME is the standard term for fibers counted by more modern analytical methods that are of equivalent size to those fibers that would be seen by PCM analysis, and includes fibers with a length to width aspect ratio of 3 to 1 or greater. EPA considered PCME fibers in our analysis of the El Dorado data to be consistent with the existing health databases and risk assessment

[1]On March 9, 2006, EPA Region 9 sent a letter to the R.J. Lee Group and the National Stone, Sand, & Gravel Association asking for additional information to support the findings and conclusions of the R.J. Lee Report.

procedures used by EPA, California EPA (Cal/EPA), the World Health Organization, and other federal agencies and international organizations. This approach was rejected by the R.J. Lee Group, which instead advocates use of asbestos fiber definitions which are not health based or supported by the majority of experts in the health community, and which would not allow comparison to the existing epidemiologic data on asbestos related cancers.

The R. J. Lee Report Claims that EPA Region 9 Misapplied Fiber Counting Protocols - The R. J. Lee Report claims that EPA Region 9 inflated the fiber counts in the El Dorado Hills air data by misapplying the International Standards Organization (ISO) method 10312 (the analytical method used by EPA to analyze the El Dorado air samples) and including PCME structures with a 3 to 1 length to width aspect ratio in our analysis. The R. J. Lee Report maintains that EPA should only have counted structures which met the general 5 to 1 aspect ratio fiber size definition described in the body of the ISO 10312 method. However, Annex C and Annex E of the ISO 10312 method specifically authorize the counting of PCME structures with a 3 to 1 aspect ratio. Another example of misleading information is the R.J. Lee Report's statistical evaluation and resulting conclusions regarding the concentrations of asbestos structures detected in the EPA air samples. All of the established EPA, National Institute of Occupational Safety and Health (NIOSH), and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels. The R.J. Lee Report did not include asbestos bundles in its analysis of the data, thereby undercounting the number of structures.

The R. J. Lee Report Claims that EPA Region 9 Misidentified Amphibole Minerals - The R. J. Lee Report concludes that EPA misidentified actinolite asbestos fibers in the El Dorado soil samples by using inappropriate extinction angle criteria. The R. J. Lee Group conclusion is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples. The R. J. Lee Report also cites an unpublished 1980 draft report to support its contention that structures found in the EPA air samples are not asbestos, and ignores a subsequent 1981 published report by the same author that actually supports the EPA approach.

The R. J. Lee Report Applies a Geologic Definition rather than a Public Health Definition to Characterize Microscopic Structures - The R. J. Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape. The EPA Region 9 approach, which is supported by most public health agencies and scientists, as well as the American Thoracic Society, is based on the following: (1) The epidemiologic and health studies underlying EPA and Cal/EPA cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, and were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at

this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"[2] (3) No well-designed animal or epidemiological studies have adequately tested the hypothesis that cleavage fragments with the same dimensions as a fiber are benign or that the human body makes any distinction, (4) Studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts, (5) There are no routine asbestos air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and ISO which differentiate between cleavage fragments and crystalline fibers on an individual fiber basis.

The R. J. Lee Report's "Virtual" Review of EPA Region 9's Air Samples is Inconsistent with Established Laboratory Practices - The R.J. Lee Group did not have access to EPA's actual air samples, nor did it collect any air samples of its own. Rather it reviewed limited pictures and spectra data of a small number of EPA's air samples and drew conclusions based on those representations. Such a virtual review is not consistent with the National Voluntary Laboratory Assurance Program (NVLAP) quality assurance procedures nor the verification methods of the National Institutes of Standards and Technology.

Federal Courts Have Supported EPA - Many of the assertions of the R. J. Lee Report are consistent with positions that the R.J. Lee Group took as an expert witness for W.R. Grace in the Libby, Montana litigation. In this litigation, the written opinions of the District and Appeals courts, while not specifically addressing the opinions of the R.J. Lee Group, rule in favor of EPA and expressly hold that EPA's experts and science are credible.[3]

Background

In October 2004, the EPA Region 9 Superfund site assessment program conducted an assessment of exposures to naturally occurring asbestos (NOA) in El Dorado Hills, California. Specifically, EPA Region 9 simulated the sports activities of children and adults at three schools and a community park and, using personal air monitors, measured asbestos levels in the breathing zones of participants. EPA Region 9 also collected samples of ambient air in the area of the sampling at the same time the simulations were conducted to serve as reference samples. The personal activity-based samples were then compared to the reference samples. The Asbestos Hazard Emergency Response Act (AHERA)[4] regulation Z-test for statistical

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[2]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

[3] See U.S. v. W.R. Grace, 280 F Supp 2d 1149 (2003): U.S. v. W.R. Grace, 429 F. 3d 1224, 1245 (9th Cir. 2005) (Although debate regarding testing methodology and data analysis is "exceedingly complex", EPA did not ignore accepted scientific principles)

[4]The Asbestos Hazard Emergency Response Act (AHERA) was passed by Congress in 1986 to provide for the inspection and mitigation of asbestos in school buildings. Regulations implementing the Act were promulgated by EPA in 1987.

significance was applied to determine whether there were any statistically significant differences between the personal exposure samples and the ambient reference samples. EPA Region 9 collected over 400 air samples and generated over 7000 data points. All of EPA Region 9's's analyses were conducted by accredited laboratories using recognized methods and procedures with strict quality assurance control, including blind performance samples to check analytical accuracy.

Amphibole asbestos, which many health scientists consider to be even more toxic than chrysotile asbestos, was found in almost all the reference and activity-based samples. Of the 29 different sets of activity-based scenario measurements, application of the Z-test determined that personal exposures from 24 scenarios were significantly elevated over the reference samples. Most importantly, the data showed that children and adults participating in sports activities in areas where asbestos occurs naturally in the surface soils, as it does in El Dorado Hills, can be exposed to asbestos fibers of health concern at up to 62 times the corresponding reference levels.

EPA Region 9 released the data from the assessment in May 2005 and held a public meeting in El Dorado Hills that was attended by more than 1000 members of the public. From the outset of the assessment, EPA Region 9 made clear to the community that EPA's only intent was to gather data on potential exposures. The community and the State and local regulatory agencies could then use the information to make decisions about the significance of those exposures and determine appropriate control measures. Both EPA Region 9 and the Agency for Toxic Substances and Disease Registry (ATSDR) have informed the community that exposure levels are a main determinant of the risk of developing asbestos-related cancers and non-cancer diseases, and that reducing the exposures reduces the risk. Consistent with its intent, EPA Region 9 has actively engaged the State and local regulatory agencies to improve naturally occurring asbestos mapping, monitoring, dust control, and regulation. El Dorado County has recently adopted more stringent dust control ordinances.

Detailed Comments on the R. J. Lee Report

R.J. Lee Finding #1: "Based on Mineralogy, Sixty-Three Percent (63%) of the Amphibole Particles Identified as Asbestos Fibers can not be Asbestos."

The R. J. Lee Report argues that there is too much aluminum in 63% of EPA Region 9's identified fibers for the fibers to be asbestiform.[5] In addition, the remaining 37% (sometimes the Report uses 35%) are not asbestos fibers based on their particle dimensions.

EPA Response

Aluminum - Analysis of the EPA Region 9 El Dorado air samples was performed using the International Standards Organization (ISO) method 10312, a state-of-the-art

[5]Asbestiform: Having the form or structure of asbestos.

Transmission Electron Microscope (TEM)[6] method with energy dispersive spectroscopy (EDS)[7] that has strict counting rules and characterizes the dimensions and chemistry of every fiber identified by the microscopist. Identification of fiber type was performed according to the general guidelines of the International Mineralogical Association (IMA) (Leake, 1997)[8], the international standard for amphibole nomenclature. This same approach for asbestos classification is recommended in the "Research Method for Sampling and Analysis of Fibrous Amphibole in Vermiculite Attic Insulation", EPA 600/R-04/004, January 2004, and was one of the tools used by Meeker et al (2003)[9] to determine the composition and morphology of amphiboles from Libby, Montana.

The R. J. Lee Report claims that 63% of the amphibole fibers identified by the EPA laboratory[10] as actinolite asbestos have concentrations of total aluminum that are too high to form asbestos fibers. According to page 2 of the R. J. Lee Report, "Particles with more than 0.3 aluminum atoms pfu [per formula unit] or about 1.5 percent Al_2O_3 cannot form in the asbestos habit due to crystal lattice constraints." To support its argument, the R. J. Lee Report cites three references. However, on close examination, two of the three references do not agree with the upper threshold limit that the R.J. Lee Group puts on total aluminum content (Leake et al, 1997) (Deer, Howie and Zussman, 1997)[11]. The third reference (Verkouteren & Wylie, 2000)[12] draws its conclusions on examination of a

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[6]Transmission Electron Microscopy (TEM) produces images of a sample by illuminating the sample with an electron beam in a vacuum, and detecting the electrons that are transmitted through the sample.

[7]Energy Dispersive Spectroscopy (EDS) uses measurement of the energy and intensity of X-rays generated when a selected area of a sample is irradiated with an electron beam to identify the mineralogical composition of a structure.

[8]B.E. Leake et al (1997). Nomenclature of Amphibole: Report of the Subcommittee on Amphiboles of the International Mineralogical Association, Commission on New Minerals and Mineral Names. American Mineralogist, Volume 82, pages 1019-1037.

[9]G.P. Meeker et al (2003). The Composition and Morphology of Amphiboles from the Rainy Creek Complex, Near Libby, Montana. American Mineralogist, Volume 88, pages 1955-1969.

[10]In this document, the terms "EPA laboratory" and "EPA Region 9 laboratory" refer to the private laboratories that conducted the analysis of the EPA soil and air samples under contract to EPA Region 9.

[11]W.A. Deer, R.A. Howie, and J. Zussman (1997). Rock-Forming Minerals: Double Chain Silicates, Vol 2, second edition, p 137 - 145.

[12]J.R. Verkouteren and A.G. Wylie (2000). The Tremolite-Actinolite-Ferro-Actinolite Aeries: Systematic Relationships Among Cell Parameters, Composition, Optical Properties, and

small set of fibrous actinolite asbestos samples which the authors partition into asbestos and fibrous "non-asbestos" byssolite using criteria which the IMA specifically recommends against, and which is inconsistent with all standard asbestos analytical methods. Perhaps most important is the fact that all three references agree that it is the IMA criteria which primarily govern the general classification of amphibole type, not the total aluminum content. These references therefore actually support the classification approach taken by the EPA laboratory.

The R.J. Lee Group did not have access to the EPA air samples to conduct their own analyses. Instead, the R.J. Lee Group looked at a limited number of photographs of the recorded EDS spectra. Interferences by other elements in the sample can affect the aluminum total in the spectra. This is especially important because the EPA samples were of air releases from soil, not processed asbestos material. Soils contain non-asbestos mineral and biological particles that can influence element totals in an EDS spectrum, most notably clay particles, which are high in aluminum. The laboratory used by EPA Region 9 identified aluminum-rich actinolite asbestos, by applying the IMA classification guidelines to its direct analysis of the actual sample.[13]

Particle Dimension - As previously stated, the R. J. Lee Report claims that 37% of the fibers counted by EPA in the El Dorado Hills air samples are not asbestos fibers based on their particle dimensions. The report claims that EPA Region 9 inflated the fiber counts by including asbestos structures which do not meet the definition of a fiber as described in ISO 10312. The general ISO 10312 method requires the counting of every asbestos structure with a length to width aspect ratio of 5:1 or greater. As directed by Region 9, the EPA laboratory counted structures with a 3:1 or greater aspect ratio. The R. J. Lee Report states that EPA erred in counting structures with aspect ratios less than 5:1. **Annex C and Annex E of the ISO method clearly authorize the counting of PCME structures with a 3:1 aspect ratio if the data are to be used for exposure or risk assessment purposes, the stated goal of the El Dorado Hills assessment. In fact, the ISO method contains numerous references to PCME fibers. PCME fibers are defined as fibers greater than 5 microns in length, and 0.25 to 3 microns in width with a 3:1 aspect ratio.[14] PCME fibers form the basis for EPA's IRIS toxicity database and the asbestos risk models of California EPA and other federal and international organizations.[15]**

Habit, and Evidence of Discontinuities. American Mineralogist, 85, p. 1239 - 1254.

[13]Personal communication with John Harris, Lab/Cor, January 2006.

[14]World Health Organization (1986). Environmental Health Criteria 53, International Programme on Chemical Safety, Asbestos and Other Natural Mineral Fibres, section 2.3.2.2.

[15]The IRIS asbestos cancer inhalation unit risk, a measure of asbestos cancer potency, is based on the EPA 1986 Airborne Asbestos Health Assessment Update (EPA/600/8-84/003F; 1986). Cal/EPA used a similar approach and data sets to derive its cancer unit risk. Both the IRIS and the Cal/EPA cancer potency values rely on human epidemiological studies that were conducted using phase contrast microscopy (PCM) analytical methods (some were midget

The R.J. Lee Group also manipulates its statistical analysis of the El Dorado Hills air data by ignoring counts of asbestos fiber bundles in its evaluations. Bundles are two or more attached parallel asbestos fibers which can have a significant health impact when they are inhaled and separate into individual fibers. Bundles were counted in the historical epidemiological studies which form the basis of our knowledge of asbestos-related health effects and EPA's IRIS database. **All of the established EPA, NIOSH, and ISO analytical methods require the counting of asbestos bundles, recognizing the significance of bundles to proper characterization of asbestos fiber levels.**

The R. J. Lee Report further states that EPA's data inflated the asbestos fiber count by ignoring the Agency's own "definition" of asbestos. To support this claim, the R.J. Lee Report cites the glossary of "Method for Determination of Asbestos in Bulk Building Materials", EPA 600/R-93/116, 1993, which states, in part, "With the light microscope, the asbestiform habit is generally recognized by the following characteristics: Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 microns." The building material analytical method is designed to detect commercially processed asbestos in items like floor tiles, roofing felts, paper insulation, paints, and mastics, not naturally occurring asbestos on air filters or in soil samples. To present the 20:1 aspect ratio for commercial grade asbestos as a universal EPA policy, and to advocate its use as an appropriate standard for analyzing air samples of naturally occurring asbestos is inappropriate and contradictory to use of the PCME dimensional criteria as a tool for assessing exposure risk.

The R. J. Lee Report also states that the diffraction pattern analyses produced by the EPA laboratory for the El Dorado Hills air samples demonstrates that the particles identified by the laboratory are not asbestos.[16] The report cites a 1980 unpublished draft study by S.J. Ring to support its conclusion. The R. J. Lee Report does not mention a 1981 published article by the same author which revises the findings such that they no longer support the conclusion of the R. J. Lee Report and, in fact, support the data produced by

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impinger data converted to PCM counts) that could not distinguish fibers that were 5 microns in length or less. PCM cannot distinguish between fibers and cleavage fragments. PCM is not as powerful as current Transmission Electron Microscope (TEM) methods (400X vs 20,000X) as TEM can see the thinner/shorter fibers. However, since EPA's (and Cal/EPA 's) toxicity database relies on human health studies that used PCM, current EPA risk procedures use the more powerful TEM method but report the PCM equivalent (PCME) fibers and only use the PCME counted fibers in a risk assessment. This is because the IRIS asbestos file specifies that only PCME fiber counts be used with inhalation unit risk for risk calculation. See also the reference cited in footnote 11.

[16]Diffraction pattern analyses irradiates a sample with x-rays and then takes an x-ray photograph.

EPA.[17]

R.J. Lee Finding #2: "The Laboratory Procedures did not Comply With the NVLAP Quality Assurance Standard."

The R. J. Lee Report says that the false positive rate in our air samples was 35% when the acceptable limit in the National Voluntary Laboratory Accreditation Program (NVLAP) is 10%.

EPA Response

The laboratories used by EPA Region 9 for analysis of the El Dorado Hills air and soil samples are accredited through the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP is administered by the National Institute of Standards and Technology, a non-regulatory agency within the U.S. Commerce Department. A large part of the accreditation process involves on-site audits performed by NVLAP-certified inspectors who review laboratory operational and quality assurance compliance parameters, including documentation proving compliance with NVLAP requirements for verification analyses. A laboratory must demonstrate that all analysts reporting data meet the false negative and false positive requirements set forth by NVLAP before an accreditation certificate is issued. To make a determination that a laboratory did not comply with NVLAP verification standards would require a very detailed examination of all laboratory generated raw data, project specific information, such as a site-specific EPA issued Quality Assurance Project Plan, laboratory instrument log books, and other data and information not supplied in an analytical report. Interviews with the laboratory manager, quality assurance manager, and involved analysts are also mandatory to make judgement on a laboratory's possible non-compliance. The R.J. Lee Report's conclusion that the EPA laboratory was not in compliance with NVLAP, based on a cursory review of count sheet and other limited data without the in-depth examination detailed above, is therefore invalid and cannot be used to question EPA's analytical results.

EPA chose NVLAP-accredited laboratories for the El Dorado Hills assessment as a minimum quality requirement. For supplemental quality assurance, the laboratories were subjected to on-site audits performed by EPA's Quality Assurance Technical Support group, and both laboratories were sent performance evaluation samples prior to analysis of the El Dorado samples. In addition, the laboratory conducting the air sample analysis was sent double blind performance evaluation samples during the sampling event. In all cases, the laboratories successfully identified the amounts and types of asbestos present on the blind samples within acceptable limits. Further, the El Dorado Hills air and soil data were validated by a third party in accordance with standard EPA quality assurance

[17]S.J. Ring (1981). Identification of Amphibole Fibers, Including Asbestos, Using Common Electron Diffraction Patterns. In Russell P.A. and Hutchings A.E. (Eds), Electron Microscopy and X-ray Applications to Environmental and Occupational Health Analysis, Vol. 2:175-198, Ann Arbor Science Publ., Inc.

procedures and were found to be acceptable for all uses.

R. J. Lee Finding #3: "The Soil Samples do not Demonstrate the Presence of Amphibole Asbestiform Minerals."

The R. J. Lee Report states that the actinolite asbestos fibers identified in the El Dorado Hills soil samples contain too much aluminum to be asbestiform and that the extinction angles of the fibers indicate that they are non-fibrous cleavage fragments. The R.J. Lee Group's analysis of 23 split soil samples from EPA's October 2004 sampling event found no asbestos in the samples.

EPA Response

Aluminum - The R. J. Lee Report states that the aluminum content of the fibers in the soil samples was too high to be asbestiform actinolite and that it was indicative of non-asbestiform actinolite and another amphibole, hornblende, which contains approximately 10-20% by weight Al_2O_3 (5.3-10.6% by weight aluminum). Both the laboratory performing EPA's El Dorado soil sample analysis and the laboratory which analyzed the EPA air samples noted significant quantities of hornblende in the samples, but did not count or report those particles as asbestos. Please see the EPA response to Finding #1 for a further discussion of the aluminum issue.

Extinction Angles - The extinction angle of a fiber evaluated by polarized light microscopy is one of many criteria used to identify mineralogical composition. The extinction angle for amphibole asbestos fibers is the difference in degrees between the long axis of the fiber and the angle at which the fiber optically disappears (the polarization direction where the light passing through it becomes "extinct") when the fiber is rotated under a polarized light microscope. The R.J. Lee Report states that amphibole asbestos fibers have a zero-degree extinction angle and that non-asbestos cleavage fragments have non-zero extinction angles. Therefore, because the EPA soil sample analysis reported extinction angles which, according to the R.J. Lee Group, averaged 12°, the report alleges EPA incorrectly identified cleavage fragments as asbestos fibers.

The R.J. Lee Report's conclusion regarding extinction angles is contradicted by the National Institute of Standards and Technology (NIST) and the major analytical methods used for analysis of asbestos in soil and bulk samples. NIST certifies and provides Standard Reference Materials (SRM) for laboratory instrument calibration and laboratory accuracy measurement. The NIST Tremolite/Actinolite SRM 1867A is a special set of three samples certified by NIST to be of ultra-high purity tremolite, actinolite, and anthophyllite asbestos and is considered the "gold standard" for asbestos analytical laboratories. The material is rigorously characterized and is accompanied by a six-page document that describes the properties of each sample. It is required that all analytical laboratories accredited by NIST/NVLAP have the material in their possession and that they use it to calibrate their operations and to test their analysts. The NIST SRM

1867A certificate which accompanies the samples of tremolite and actinolite states that the reference tremolite can have an extinction angle of up to 16.6 ± 0.3° and that the actinolite can have an extinction angle of up to 15.9±0.2°. When the EPA laboratory processed the NIST actinolite standard in the manner of the El Dorado Hills soil samples, the extinction angles of the fibers in the processed standard sample were consistent with allowed maximum extinction angles for tremolite/actinolite asbestos (~ 10° to 20°) and the extinction angles of the fibers seen in the EPA soil samples.[18]

Further, the laboratory methods of EPA, NIOSH, and other agencies for analysis of asbestos in bulk material all state that tremolite-actinolite asbestos fibers may have zero (parallel) or *non-zero* (inclined or oblique) extinction angles. EPA Method 600/R-93/116[19], the standard method used by all NIST/NVLAP accredited laboratories to test building materials for the presence of asbestos, states in Table 2-2, Optical Properties of Asbestos Fibers, that tremolite-actinolite asbestos has extinction "parallel and oblique (up to 21°)." NIOSH Method 9002[20], the method used for analysis of the El Dorado Hills soil samples, states directly that actinolite and tremolite fibers exhibiting inclined extinction are to be considered asbestos. The method further states that "If anisotropic fibers are found (during PLM analysis), rotate the stage to determine the angle of extinction. Except for tremolite-actinolite asbestos which has oblique extinction at 10-20°, the other forms of asbestos exhibit parallel extinction... Tremolite may show both parallel and oblique extinction."[21]

R.J. Lee Finding #4: "The ISO 10312 Analytical Method can not Distinguish Between Asbestos Fibers and Non-Asbestos Cleavage Fragments."

The R.J. Lee Report states that the ISO 10312 method contains the disclaimer that "The method cannot discriminate between individual fibers of asbestos and non-asbestos analogues of the same amphibole material," and, therefore, EPA inflated the asbestos air concentrations by counting "cleavage fragments."

EPA Response

The ISO 10312 method cannot differentiate between fibers and cleavage fragments with

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[18]M. Bailey (2006). Identification of Asbestiform Tremolite/Actinolite. Naturally Occurring Asbestos Workgroup Meeting Presentation.

[19]USEPA (U.S. Environmental Protection Agency) (1993). Method for the Determination of Asbestos if Bulk Building Materials. EPA Method 600/R-93/116.

[20]NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2).

[21]NIOSH (National Institute for Occupational Safety and Health) (1992). Asbestos (Bulk) by PLM.. Method 9002 (Issue 2). Qualitative Assessment, Item c, page 4.

the same dimensions and chemical composition. No routine analytical method has a protocol for distinguishing fibers from cleavage fragments on an individual particle basis. Additionally, from a health standpoint, there is no evidence that supports making the distinction.

Cleavage fragment is a geologic term which refers to structures that form when non-fibrous forms of asbestos minerals split along crystallographic planes, as opposed to asbestos fibers which form from crystalline growth. The R.J. Lee Report maintains that there is a toxicological difference between asbestos structures which formed as fiber crystals and fibers which formed by cleavage plane separation. Page 3 of the R.J. Lee Report states that cleavage fragments are "not known to produce asbestos-like disease." **It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry (ATSDR) and National Institute for Occupational Safety and Health (NIOSH), and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine minerals that are asbestiform and meet the size definition of PCM fibers, should be counted as asbestos, regardless of the manner by which they were formed.** There are four reasons why the health agencies have taken this position: (1) The epidemiologic and health studies underlying EPA, and California EPA, cancer risk assessment methods were based on exposures to both cleavage fragments and fibers, but were unable to distinguish between the two, (2) The most recent panel of experts to review asbestos risk assessment methods, the 2003 Peer Consultation Panel convened by EPA, concluded that "it is prudent at this time to conclude equivalent potency [of cleavage fragments and fibers] for cancer,"[22] (3) No well-designed animal or human epidemiological studies have been conducted to date to test the hypothesis that cleavage fragments with the same dimensions of a fiber are benign, or that the human body makes any distinction, and studies that purport to show that cleavage fragments are benign are questioned by many asbestos health experts,[23] (4) There are no routine air analytical methods, including those used by EPA, NIOSH, the Mine Safety and Health Administration (MSHA), the American Society for Testing and Materials (ASTM), and the ISO which differentiate between cleavage fragments and crystalline fibers.

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[22]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page viii.

[23]Both Addison (Addison J, Davies LST. 1990. Analysis of amphibole asbestos in chrysotile and other minerals. Ann Occ Hyg, Apr;34(2):159-75) and members of the U.S. EPA 2003 Peer Consultation panel raised concerns about interpretation of the Davis study (Davis JM, McIntosh C, Miller BG, Niven K. 1991. Variations in the carcinogenicity of tremolite dust samples of differing morphology. Ann NY Acad Sci, Dec;643:473-90), which attempted to compare the toxicity of asbestos fibers and cleavage fragments. These concerns reflected the lack of peer review, use of intra peritoneal injection instead of inhalation exposure, significance of mesotheliomas caused by structures reported as cleavage fragments, purity of the cleavage fragment samples and issues related to fiber dimensions.

In terms of epidemiological data and health outcomes, the cleavage fragment argument is without merit. For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.

There are no recognized analytical protocols, including those used by EPA, NIOSH, MSHA, ASTM, and ISO, which include criteria to differentiate between cleavage fragments and crystalline fibers. All these methods require that structures which meet their definition of the specific counting rules for an asbestos fiber be counted. The requirements are based on the fact that, in the words of an expert from the United States Geological Survey, "At a microscopic level, distinguishing between these forms on single [asbestos] particles, can be extremely difficult to impossible."[24] As noted above, R.J. Lee made a very similar claim with regard to cleavage fragments as the expert witness for W.R. Grace in the Libby, Montana, Superfund cost recovery litigation. The EPA analytical experts who reviewed the R.J. Lee Group's testing methodology related to the Libby site found that the R.J. Lee laboratory could not demonstrate any reliable criteria with which to distinguish, at the microscopic level, asbestos cleavage fragments from asbestos fibers of the same size, shape, and composition. The Ninth Circuit Court of Appeals recognized the competing scientific arguments but found that EPA's position was consistent with the record of evidence and accepted scientific principles.[25]

R.J. Lee Finding #5: "Applying the Latest Science and Definitional Techniques, the El Dorado Hills Study Shows no Significant Exposure to the Type of Amphibole Asbestos Fiber Connected To Health Risk."

The R. J. Lee Report claims that the latest science for measuring the risk posed by asbestos is the Berman-Crump Asbestos Risk Assessment Protocol ("Berman-Crump") which proposes that amphibole asbestos fibers which are more than 10 microns long and less than 0.5 microns wide (protocol fibers) are the most toxic. Of the 2,386 fibers which the R. J. Lee Report states the EPA laboratory identified, the R.J. Lee Report concludes that only 7 fibers meet the "Berman-Crump" definition. Therefore, the R.J. Lee Group maintains that EPA has overstated the risk from exposure to asbestos fibers in El Dorado Hills.

EPA Response

The "Berman-Crump" protocol that the R.J. Lee Report references is in fact a draft EPA method. EPA had the method reviewed by a peer consultation panel in 2003. The panel made a number of important recommendations that must be addressed before the method can be used for EPA risk assessments. A number of important revisions have been made

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[24]G.P. Meeker, USGS, (2002). Review of Expert Report of R.J. Lee.

[25]U.S. v. W.R. Grace, 429 F.3d at 1245.

to the draft method since 2003, but at this time the method has not been independently peer reviewed. It will not be adopted by EPA as a risk assessment tool unless and until it passes rigorous internal and external peer review.

The expert peer panel has recommended that the fiber size for the draft EPA risk assessment method be adjusted to include fibers greater than 5 microns in length and up to 1.5 microns in width.[26] The change is designed to account for lung deposition of fibers that results when fibers are inhaled through the mouth, and not filtered by the nasal passages. The broadening of the fiber definition to include inhalation by "mouth breathers" is especially relevant to the El Dorado Hills data. Our investigation measured personal asbestos exposures of individuals participating in sports activities, where physical exertion would likely increase breathing through the mouth. **The PCME fibers counted in the EPA air samples are actually consistent with the latest science of EPA, as reflected in the recommendations of the peer consultation panel.** In addition, the EPA peer consultation expert panel recommended that cleavage fragments be treated as any other asbestos fiber of the same morphology and chemical composition.[27]

EPA Region 9 focused on obtaining an accurate count of PCME structures, consistent with our risk assessment protocols and those of Cal/EPA and other health agencies. The counting rules which EPA set for the laboratory were designed to stop counting when a statistically-significant number of PCME fibers were detected. By concentrating on PCME structures, other fiber size classifications may not have been counted to statistical significance. This may have resulted in under counts of other fiber sizes (e.g. the "Berman Crump" protocol fibers referred to in the R. J. Lee Report). **EPA Region 9's study counted PCME structures so that the data could be directly compared to human health epidemiological studies.** These epidemiological studies form the basis for risk assessment models currently used by EPA, Cal/EPA and other federal agencies and international organizations.

R. J. Lee Report Peer Reviews

The R. J. Lee Report was reviewed by three individuals, although research of one of the individuals was extensively quoted in the report and therefore the independence of the reviewer is debatable. The three reviewers generally agree with the conclusions of the R. J. Lee Report regarding aluminum content, fiber chemistry, cleavage fragments, and extinction angles.

Both the R. J. Lee Report and one of the reviewers support use of the original "Berman-

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[26]USEPA (U.S. Environmental Protection Agency) (2003). Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, Final Report. Office of Solid Waste and Emergency Response, Washington D.C. Page 5-5.

[27]Ibid, page 5-1.

Crump" protocol and calculate a "Berman-Crump" fiber air concentration of 0.0002 fibers/cubic centimeter, using the EPA fibers which they assert meet the "Berman-Crump" definition. The peer reviewer then compares that concentration with an ambient concentration of 0.0008 fibers/milliliter measured in New York City, and states that the "Berman-Crump" value in El Dorado Hills is extremely low. This comparison is flawed for at least two reasons. Significantly, the New York City numbers are based on fibers counted against a totally different size classification (essentially comparing apples to oranges), but **the reviewer also fails to recognize that a concentration of 0.0002 f/cc translates in the protocol to an increased cancer risk of 1 in 1,000 exposed individuals.** This number is disturbingly high and is outside the acceptable cancer risk ranges of EPA, Cal/EPA, and most other state and federal health agencies.

Conclusions

EPA Region 9 has carefully reviewed the R. J. Lee Report and believes that it makes largely unsupported and incorrect conclusions about the EPA Region 9 El Dorado Hills Naturally Occurring Asbestos Exposure Assessment. EPA Region 9 has asked the United States Geological Survey (USGS) to conduct an independent study of the El Dorado County area to address several mineralogical questions raised by the R. J. Lee Report. The USGS study will use sophisticated analytical techniques (such as electron probe micro analysis) to more completely characterize the naturally occurring asbestos in terms of mineral identification and particle morphology.

All of the EPA Region 9 work in El Dorado Hills was, and continues to be, consistent with the EPA's standard operating and quality control procedures for asbestos work throughout the country.

Exhibit 162

Johnson & Johnson

BABY PRODUCTS COMPANY

for Talc testing
mtg c J. Bender
Slu.

October 4, 1984

SKILLMAN, N. J. 08558

TO: B. Semple, M.D.

SUBJECT: Evaluation Program for Talc

The following tests are run on all biweekly composite samples from Windsor Minerals and on yearly International Talc Audit samples.

1) X-ray diffraction for qualitative minerological composition.

2) Slow scanning x-ray diffraction for amphibole minerals (CTFAJ4-1).

3) Presence of free crystalline silica (quartz) by x-ray diffraction (CTFAJ6-1).

In addition, a quarterly composite is made from the biweekly Windsor Minerals samples and analyzed by Transmission Election Microscopy (BPC Test Method 7024) for serpentine minerals.

James A. Molnar

JAM:rp
0522R

Exhibit 163

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
DOCKET NO. MID-1809-17AS
APPELLATE DOCKET NO._____

DOUGLAS AND ROSLYN BARDEN,

Plaintiffs,

v.

BRENNTAG NORTH AMERICA, et al.,

Defendants.

TRIAL

(VOLUME 1 OF 2)

MID-L-0932-17AS

DAVID CHARLES ETHERIDGE AND
DARLENE PASTORE ETHERIDGE,

Plaintiffs,

v.

BRENNTAG NORTH AMERICA, et al.,

Defendants.

MID-L-7049-16AS

D'ANGELA MCNEILL-GEORGE,

Plaintiff,

v.

BRENNTAG NORTH AMERICA, et al.,

Defendants.

MID-L-6040-17AS

WILLIAM AND ELIZABETH RONNING,

Plaintiffs,

v.

BRENNTAG NORTH AMERICA, et al.,

Defendants.

Place: Middlesex County Courthouse
56 Paterson Street
New Brunswick, New Jersey 08903

Date: Wednesday, January 29, 2020
9:05 a.m.
(Volume 1 of 2)
(Pages 1 - 200)

BEFORE:
HON. ANA C. VISCOMI, J.S.C. and JURY

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COURT OFFICER: All rise. Jury entering.
(Jury enters.)
THE COURT: Good morning. Please be seated. Make sure cell phones are turned off.
Good morning, Dr. Sanchez. If you could please come back up.
Today is January 29, 2020. This is the continued trial in the matter of Douglas and Roslyn Barden versus Johnson & Johnson, David and Darlene Etheridge versus Johnson & Johnson, D'Angela McNeill versus Johnson & Johnson, and William and Elizabeth Ronning versus Johnson & Johnson.
May I have appearances, please, for the plaintiff.
MR. PANATIER: Yes. Good morning, your Honor. Good morning, jurors. Chris Panatier, Moshe Maimon, Chris Placitella for the plaintiffs in the case, your Honor. Thank you.
THE COURT: Thank you.
For the defendants.
MS. BROWN: Good morning, your Honor. Good morning, jurors. Alli Brown, Morty Dubin, Kevin Hynes, for J&J.
THE COURT: Thank you.

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So, members of the jury, you may recall yesterday we commenced with the defendants' portion of this case and their expert witness, Matthew Sanchez, is testifying now on cross-examination.
Mr. Panatier, you may continue.
MR. PANATIER: Okay. Thank you, your Honor.
THE COURT: Just a reminder, you were here yesterday and placed under oath. We are not going to re-administer the oath, but just a reminder you are under oath.
THE WITNESS: Understand.
THE COURT: There is a microphone that is placed there now that will amplify your voice.
THE WITNESS: Thank you.
M A T T H E W S A N C H E Z, previously sworn.
CONTINUED CROSS-EXAMINATION BY MR. PANATIER:
Q. You have a personal speaker now.
So yesterday you and Mr. Dubin spent some time going through these boards. I'm sure you recall all that?
A. I do.
Q. So to make it very clear, nothing,

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and nothing that was on these boards was inaccurate?
A. I'm sorry?
Q. Nothing on these boards failed to report exactly what was in the documents that they're talking about, correct?
A. I believe that's correct.
Q. Okay. So, you know, many times you were asked this question, does that say asbestos.
Now, let's just take, for instance, tremolite asbestos. Before you have tremolite asbestos you have to have tremolite, right?
A. Well, yes, tremolite asbestos would also be, the correct mineral name for the identification would also have tremolite part of it.
Q. You have to have the actual mineral tremolite present; true?
A. That's true.
Q. And so same question for something like anthophyllite; if you have anthophyllite asbestos, you have to have anthophyllite, the mineral, present, correct?
A. Correct. It would be the asbestiform variety of anthophyllite, yes.
Q. And if we go to some of the earliest studies that Johnson & Johnson had, and you're

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familiar with Battelle Memorial?
A. I am.
Q. They were looking for the presence of certain minerals, right?
A. I don't know if that was their purpose. A lot -- they were doing it for a variety of purposes and they were reporting on minerals they were seeing, yes.
Q. I don't want to have to get too detailed with you on this, but within these talc deposits there can be upwards of 20 or 25 other minerals in with the talc, correct?
A. Depending on the deposit and other factors, there could be many minerals present.
Q. Right.
And you're aware from looking at the Battelle studies in the '50s, '60s and early '70s, that they were really focused on about three or four; they looked at chlorite, they looked at dolomite, they looked at tremolite. Correct?
A. I don't understand that question. I'm sorry.
Q. They looked at, of the 20, 25, however many possible minerals could be present in the talc, they looked at about four, five of them,

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correct?
A. I don't understand that. They were characterizing what they saw, dominant in the talc. Talc was the dominant mineral. Then you're going to be chlorite and the dolomites and carbonates would be the next most frequent, and then on some of the reports there was a small amount of tremolite they observed.
Q. In fact, tremolite came up quite a bit in those reports, correct?
A. Well, many of those are testing of the same samples, so yes, you wouldn't expect a repeat finding if it was actually there.
Q. You're not saying these are repeat samples, are you?
A. If you look at, many of those tests are of Italian 1 and Italian 2 that are repeated over and over again, so a lot of those are just testing of the same material for different purposes.
Q. Italian 1 and Italian 2 were two different grades that were coming out of the same mine, correct?
A. That's correct.
Q. All right. So you guys spent some time going through the boards and looking at the

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documents and I'd like to do a little bit of that, too, to sort of give us the full picture on the story. And I think you said yesterday, you said you really have to dig into the documents and learn what you can, right?
A. As much as possible, yes.
Q. So I'd like to do that a little bit.
The first thing I want to do is show you, this is the Fred Pooley 1972 Italian study that he did, and you guys talked about that, correct?
A. We did.
Q. It's like 150 pages long. But if you go right to the conclusions, it says this: "The talc specimens were, however, plate-like in appearance with varying quantities of lath-like particles coupled with fibers which were textile in appearance.
"Both lath and textile types of particles were not composed of minerals associated with the commercial asbestos industry. Particles formed from amphibole mineral found at the mine were hardly fibrous in character, the majority of the tremolite breaking to give compact particles."
Right? Did I read that correctly?
A. You did.

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Q. He says they were hardly fibrous, right?
A. That is the word he uses, yes.
Q. Now, when you dig into the documents, have you looked at Dr. Pooley's testimony by -- that was, I believe, Mr. Bicks, who is Mr. Dubin's partner, was present at the deposition.
Have they shown you this testimony about this section?
A. I don't believe so.
Q. Let me show it to you and ask you some questions.
MR. DUBIN: Your Honor, I would object.
THE COURT: Sure.
(Sidebar.)
MR. DUBIN: I didn't understand he was intending to cross-examine this witness with the portion of the transcript they're not introducing into evidence that he says he hasn't reviewed. I wasn't even allowed to ask him about things like the Blount transcript that he has reviewed and considered for purposes of his opinion.
It's not part of his opinion in the case, nor litigation deposition of Dr. Pooley, what

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I understand your Honor's guidelines to be part of the record for purposes of punitive damages.
MR. PANATIER: The Blount situation was one of what the disclosure was and what the four corners of the report was. That was a scope issue having to do with notice. This is not. This is what have you reviewed when he commented on this. And Dr. Pooley -- I can actually lay a foundation. I can ask him --
THE COURT: Let him just complete, let him finish --
MR. DUBIN: Okay.
THE COURT: -- what he was saying.
MR. PANATIER: I can lay a foundation. I can ask him if Dr. Pooley clarified what he meant by hardly fibrous. Would you like to see it? I'm happy to do that. If he says no, fine.
MR. DUBIN: That is a gamesmanship technique to ask that in front of the jury to try to get something in that's not admissible. He also looks like he's going to hand him a page of what was a full day deposition which the witness would need an opportunity to have reviewed in full before answering questions.
MR. PANATIER: An expert can consider

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matters that are hearsay, that are inadmissible and he can evaluate it. If he believes he needs more context, it's three questions. And if he says I need more context, he can say he needs more context. But he's not gonna. And this came in in Phase I. I crossed John Hopkins with it.

THE COURT: Okay. So during his direct you went through plaintiffs' boards and went through documents --

MR. DUBIN: Correct.

THE COURT: -- as to whether or not it was asbestiform, non-asbestiform, how it was categorized. Was this document one that plaintiff was --

MR. PANATIER: This is.

THE COURT: I'm sorry, the defendants went through on direct?

MR. PANATIER: This document is.

MR. DUBIN: I did not go through -- this is a multipage deposition. We're talking about historical documents what they actually said. He's questioning him now about what the historical documents says which goes to whatever Johnson & Johnson's knowledge was at the time. If this witness -- we're now getting into litigation

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depositions.

First of all, the witness would need an opportunity to review the deposition and comment on whether the plaintiffs would put that into evidence if they wish, but not with this witness. Otherwise, I don't see why I can't ask him about things that Dr. Blount said about her findings.

THE COURT: Well, he was limited to the four corners of his report. Dr. Blount was not in the four corners of his report. Here this is a document, the underlying document which you went through with him on direct.

This is permissible cross-examination and you'll have the opportunity for redirect.

MR. DUBIN: I would ask the witness be given a full copy of the transcript and enough time to read the transcript before being asked the questions about two lines from the transcript. I think that is only fair.

THE COURT: I think that you could find if counsel is mischaracterizing those sections you have the opportunity on redirect.

MR. DUBIN: Do you have the full transcript?

MR. PANATIER: I don't have --

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MR. DUBIN: Then --

THE COURT: You will have it before redirect. Have someone work on that.

MR. PANATIER: We will.

(Sidebar ends.)

THE COURT: Proceed.

BY MR. PANATIER:

Q. All right. So I'm going to hand you an excerpt from Dr. Pooley's deposition and do you see at the top it says, "Fred Pooley, Ph.D."?

A. It does.

Q. That's the same Pooley that authored this report and the Pooley that you talked about at length?

A. Yes.

Q. Right? Okay.

If you go to the second page there's a reference, there's some highlights there and there's a reference to Mr. Bicks, and the question you're asked, the question you're asked is, "Mr. Bicks has inadequately quoted this report. Particles formed from the amphibole mineral found at the mine were hardly fibrous."

And you and I just read that, right?

A. That's correct.

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Q. Dr. Pooley said yeah.

Next question, "The majority broke to give compact particles. They got too small. Doesn't mean all of them did, does it?"

And Dr. Pooley, he has to ask it again, "Doesn't mean all of them did, does it?"

And Dr. Pooley says nope.

The next question was, "So he didn't quote it here, but you found tremolite that was asbestiform that didn't break apart, didn't you?"

And he said, "Yes, a few particles. Yes."

Correct?

A. You read that correctly.

Q. Okay. Dr. Pooley did find asbestiform tremolite, correct?

A. No. That is not what he says in his report and this question is confusing.

Q. Well, we can look at it with our eyes. We just saw this section here.

Oops, can I go to the Elmo, please? Thank you.

We just saw this section here, "particles formed from the amphibole mineral found at the mine were hardly fibrous," right?

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A. Yes.
Q. And the lawyer there asks this question, "Doesn't mean all of them did, does it?
"Nope.
"So he didn't quote it here, but you found tremolite that was asbestiform that didn't break apart, didn't you?
"ANSWER: Yes, a few particles. Yes."
Did I read that right?
A. You did.
Q. When you're talking about TEM with the electron microscope, if you see just a few particles in this tiny, tiny, tiny little bit, depending on the dilution and all of that, you could be talking about thousands to millions to billions of fibers, depending; correct?
A. I don't know if you'd ever get to billions on only a few, but again, it would depend on the math on where the concentration would go.
THE COURT: Counsel, for the record, could you identify that Pooley report by exhibit number?
MR. PANATIER: I'm sorry. We didn't have it marked, but we would mark it as, I think we

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have an S-4 --
MR. DUBIN: Defense 7038.
THE COURT: Defense 7038?
MR. DUBIN: I believe so.
MR. PANATIER: The Pooley report?
THE COURT: Yes.
MR. PANATIER: We would mark the deposition excerpt just as S-4 for identification.
THE COURT: Thank you.
(S-4 was marked for identification.)
BY MR. PANATIER:
Q. You also talked about Colorado School of Mines, some of their findings, right?
A. I did.
Q. And some of the things that I had put on our boards?
A. That's correct.
Q. You talked about this document from July 23rd, 1973?
THE COURT: For the record, what was that marked as?
MR. PANATIER: I don't remember. They didn't have -- they didn't have the exhibit numbers up that I saw.
THE COURT: You're going to have

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to --
MR. DUBIN: I'm sorry, which document?
MR. PANATIER: July 23rd, '71. Do you guys have it marked?
MR. DUBIN: I'm sure we did.
MR. HYNES: That's 2386.
THE COURT: Thank you very much.
MR. PANATIER: This is 2386.
BY MR. PANATIER:
Q. All right. July 23rd, 1971. They're looking at the baby powder talc, correct?
A. One of the samples, yes.
Q. Right.
And they said, "Trace amounts of a mineral with a lattice spacing of 3.05 A was noted in the head and tail samples," correct?
A. Correct.
Q. They don't even identify what amphibole that would be, correct?
A. That's not what I said. May I go further?
Q. Sure, go ahead.
A. Okay. Thank you.
When you have a mineral and you do

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your X-ray diffraction on it, we showed you the one, we showed the jury the one graph we had all those different peaks. So every mineral will have a set of peaks. Some of those peaks will be unique to that mineral, some of the peaks will not be unique to that mineral.
So the specific peak that would correspond to that 3 Angstrom, that 305 A, as they referred to in the document, that is not a unique peak for an amphibole. That could be any number of materials. The unique peak for amphiboles are at different positions which they don't make any mention of.
So you assume they weren't seeing the unique features of the amphibole, but they had some peak that they couldn't match up. An amphibole is only one of many possibilities that could match for that peak.
Q. Okay. Well, I'm going to show you Plaintiffs' Exhibit 3695-25. This is eight days later. August 3rd.
Do you see that?
A. I do.
Q. Do you see where they say anthophyllite, and they say 3.05 A?

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A. That's correct. That is a, that is one of many peaks for anthophyllite.
Q. Okay. So they identified in the Vermont 66, 305 A, eight days later, they identified that as anthophyllite, correct?
A. No. That's incorrect. They're simply reporting, so if you pull up the -- may I explain further? I'm sorry.
Q. I'm just going to ask you, sir, do they identify eight days later anthophyllite as having major anthophyllite lines at 8.5 A and 3.05 A?
A. That is correct. Anthophyllite would have -- those are two of the many reflections for anthophyllite that they identified there.
Q. Okay. Let's look at, this is Plaintiffs' Exhibit 2808, because I want to now get the full story. You said you had to dig into the documents, so let's do that a little bit.
This is June 30, 1971. And you can see here, Colorado School of Mines. And they report that "Based upon X-ray diffraction and microscopical analyses of the Vermont finished product plant run sample 344 L" -- now, you know 344 L was a production sample of Johnson's Baby Powder, correct?

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A. I believe it was.
Q. -- "and six monthly Vermont finished product samples, only very trace amounts of tremolite actinolite were identified." Right?
A. That's correct.
Q. They looked at seven things, they looked at one 344 L, which was baby powder, and then they looked at the finished product samples for six other monthly Vermont runs of the product, correct?
A. I don't know the number here based on what you're showing me.
Q. Right there it says six.
A. I apologize.
Q. Okay.
A. Thank you.
Q. No problem.
A. I'm sorry, I need to go back, I don't know the number of samples. They're just saying samples that represented six monthly runs. I just want to make sure we're talking about the correct number of samples.
Q. That's fine. They tell us.
MR. DUBIN: Do you have a copy?
MR. PANATIER: I'm pulling these straight out of the admitted exhibits that we've --

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MR. DUBIN: I am just asking --
THE COURT: Excuse me, can you provide a copy to the witness?
MR. PANATIER: Your Honor, I pulled these straight out in response to cross. They have been provided to counsel.
THE COURT: Does anyone have a copy for the witness?
MR. PANATIER: I'll let the witness look at it first if he wants to look at it.
THE COURT: Thank you.
MR. PANATIER: Here you go.
(Handing.)
MR. DUBIN: What is the exhibit number?
MR. PANATIER: That was 2808.
BY MR. PANATIER:
Q. That's their methodology that they go through and they detail, correct?
A. Yes, they do talk about their methodology here.
Q. This next document, I think, might help us understand whether they were looking at separate samples. If you want to look at this. This is Plaintiffs' Exhibit 2378. I'll show it to

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you. July 7, 1971.
Does this help right here?
A. Let me finish this document.
Q. Okay.
A. I'll go to the next one. Thank you.
MS. BROWN: Your Honor, we do have extra copies of what counsel's asking about that we can give to the witness.
THE COURT: Thank you very much.
MS. BROWN: Chris, this is the first one.
BY MR. PANATIER:
Q. Now we're looking at this one, and this one is from July 7, 1971, right?
A. Yes. This one is.
Q. Do you see here that they look at sample 344 L and then six production samples, right?
A. Okay.
Q. And those are all different samples, correct?
A. Yes.
Q. So they are six independent samples, plus a seventh finished product sample, right?
A. Correct.
Q. And you could see, sir, that they

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find tremolite/actinolite in six of the seven, including the bottle of baby powder, 344 L, right?
A. Again, I'm not sure if 344 L is a baby powder, but yes, they identify trace tremolite actinolite by X-ray diffraction in that sample.
Q. And I asked you if that was a bottle of baby powder, you said you believed it was?
A. I'm trusting you on that. I don't know for sure without checking more documentation.
Q. Okay. Well, you told this jury about the Langer story yesterday, right?
A. Um-hum.
Q. And the bottle that he was looking at was 344 L, correct?
A. Okay.
Q. Okay. So here they report, and this is on July 7, they report tremolite/actinolite in six production samples and a bottle of baby powder, right?
A. Five production samples and the 344 L sample, yes.
Q. Correct.
One of the production samples was non-detect, correct?
A. True.

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Q. The next exhibit is Plaintiffs' Exhibit 2385. I'll let you look at it and then I'll retrieve it. Okay?
A. Okay.
Q. Okay. You got it?
A. I do.
Q. So this is now July 29. So we just looked at July 7. Now we're looking 22 days later. And you can see this is an internal memo, right?
A. I see that.
Q. And you can see here it just says, "The talc used in Johnson's Baby Powder is obtained from a selected mine in Vermont where the ore consists mainly of platy talc with only trace amounts of fibrous minerals tremolite/asbestos contaminated talc."
They call them fibrous minerals, correct?
A. Correct.
Q. "It is free of chrysotile fibers which may be called pure asbestos by the layman," and they go on and they talk.
But down here you could see that they have, they're discussing the Colorado School of Mines' research reports that we have now looked at,

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right; June 30 and July 27, correct?
A. They do reference that. Yes.
Q. Now we go four days later. There's a meeting at the FDA on August 3rd, 1971; correct, sir?
A. I believe so.
Q. And this is Plaintiffs' Exhibit 2390. I'll let you peek at this. Here is a copy if you want.
A. Yeah. That's fine.
Q. Here's the last one, if you want to look at it.
A. Thank you.
Q. All right. So August 3rd, 1971, there's a meeting at the FDA. And if we want to know who was there, at the end there's a attendance list, correct?
A. Yes. On page 6.
Q. Johnson & Johnson brought one, two, three, four, five, six, seven, eight, nine people, correct?
A. Appears correct.
Q. Mr. Caneer is from the Colorado School of Mines, right?
A. That's correct.

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Q. And you could see that they --
A. Which page are you on now?
Q. I'm just paging through it just to give us a general appreciation.
Each person or many of the people actually stood up and presented, correct?
A. That's typically what would happen at a meeting like this, yes.
Q. All right. The next exhibit is 2391, also 8/3rd. To get our bearings, what I'm showing you now is Johnson & Johnson's minutes, their memo. And now I'm going to show you the FDA's. Okay? This is the FDA's copy. It's not quite as good.
But if you could see at the top that's 8/3/71. And feel free to page through it, if you'd like.
All right, sir. On the first page we could see this is from August 3rd, '71, and this is the FDA version.
Do you see that?
A. Yes, I do see that.
Q. And it says, "To specify a laboratory purpose -- to specify a laboratory procedure for the determination of asbestos in cosmetic talc powders which will give consistent, meaningful results, this

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may require answers to questions such as: Is there a need to count not only asbestos fibers but also non-asbestos fibers and fibrous talc," and it goes on, correct?

A. Correct.

Q. I just want to go to the attendance list on the next page. Starts here. Malcolm Ross, and then you see the folks from Johnson & Johnson, right?

A. Yes.

Q. And there's Mr. Caneer again, he's from Colorado School of Mines; true?

A. Correct.

Q. And on the next page they have presentations, Analytical Methods For Asbestos. And there's Mr. Caneer again from Colorado School of Mines, right?

A. Correct.

Q. If you turn to, again, this thing is a rough copy, if you go to the page at the top it's marked 5. So under the date --

A. Yes.

Q. -- go halfway down, there's what Mr. Caneer said. "W.T. Caneer, Colorado School of Mines Research Institute. Reviewed petrographic and

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electron probe studies of J&J." He's talking about the Johnson & Johnson talc, right?

A. Correct.

Q. "Showed clean fiber"?

A. That's what it says.

Q. Right?

Do you know what that means?

A. By that term, no, I'm not sure what the author of this memo meant by that.

Q. Okay. Whatever he's saying, he's saying the powder was clean somehow; fair?

A. Well, again, I don't know. Just says, "showed clean fiber." You'd have to ask the person who made the minutes to know what he meant at that time.

Q. Okay. Then there was a mention here about Mr. Geiger or Geiger. Geiger or Geiger was with McCrone, correct?

A. I'm sorry, what page are you on.

Q. The very next page, page 6.

A. Yes. Mr. Geiger was at McCrone.

Q. And the author of this memo just says, "Geiger questioned some of Art Langer's identification of chrysotile fibrils. This was a smokescreen, but a good counter-offensive to Langer

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finding chrysotile everywhere." Right?

A. You asked me if you read that correctly?

Q. Yeah.

A. You read that correctly.

Q. That's what's in the reported minutes, right?

A. Whoever wrote the minutes, that was their interpretation.

Q. Right.

So we know there's this meeting on 8/3/71. So before that, we have the results of the 344 L, the baby powder, and the six production samples where five are positive for tremolite actinolite, correct?

A. For those minerals, yes.

Q. Then within a month or a month and a half, there's a meeting at the FDA where Mr. Caneer says the Johnson & Johnson samples represented clean fiber, whatever that means, right?

A. I don't know what Mr. Caneer said. That's what -- whoever wrote the minutes, that's what they wrote. I don't know what Mr. Caneer would have said at that time.

Q. That's fine.

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This is Exhibit 2381, Plaintiffs' Exhibit 2381. This is three days later. And this is a memo that you and Mr. Dubin went over yesterday. This is three days after that meeting with the FDA. And this is from the Colorado School of Mines to Johnson & Johnson, right?

A. Correct.

Q. And it's from Maurice Pattengill, M.G. Pattengill, right?

A. Yes.

Q. And it says, "After attending the Washington meeting August 3rd, '71, and listening to the arguments and data presented, I have the following to add to the data previously sent to you concerning the Vermont talc samples. In the report of July 7, 1971, there is some question relative to the presence of tremolite actinolite."

Remember, this is the one where they found the tremolite actinolite in the baby powder and the five of six production runs, correct?

A. That's correct, by X-ray diffraction, yes.

Q. He says there's some question. "The samples were prepared in a room that was not entirely clean and were prepared in conjunction with

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standard type asbestos samples. Subsequent X-ray work on six monthly production samples and the 344 L product sample shows no definite indications of any asbestos type minerals within our limits of detectability. The trace amounts I saw were evidently contamination from standard asbestos samples."

So three days after the meeting with the FDA, this guy from Colorado School of Mines writes to Johnson & Johnson and said, you know, I've been thinking about it, and I just realized that it was actually contamination, right?

A. That's what he reports. Yes.

Q. Now, if you are aware that there's a contamination issue in a lab, right, you immediately rerun the samples, don't you; clean it up, you rerun it?

A. Once you become aware there may be an issue, you would look into it. So depending when your knowledge came that there may be an issue with contamination is when you would take action.

Q. And apparently this fellow's knowledge came three days after a meeting with the FDA, correct?

A. That's what he states.

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Q. And he said, "After attending the Washington meeting," right?

A. Yes.

Q. And it's signed by Maurice Pattengill, right?

A. That's correct.

Q. Maurice Pattengill.

Here's the meeting. Let's go to the attendance list. Did Maurice Pattengill attend this meeting according to the attendance list?

A. Well, the list is a prospective participants list. So again, we're talking about he may not have participated. He may have been in attendance, but he was not giving any information or presenting any information.

Q. Hold on, hold on. Look. Look at the top. "The following people attended the symposium."

A. Well, I'm looking at the FDA minutes which talks about participant list.

Q. So he's not on either. He's not on the prospective participants list and he's not on the attendance list, is he?

A. I would have to check, but if you're asking me the question, I assume he was not in attendance, or at least he's not recorded as being

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in attendance.

Q. And there's the whole list. Do you see his name on it?

A. I can't do that. I'm going to go crazy.

Q. Here.

A. That's fine. I have the document here.

You are correct, I do not see his name.

Q. So when we dig into the documents what we see is that they had detected what they detected. Then they had a meeting at the FDA. Then a guy who wasn't there said after being there, I remembered now that it was all contamination.

Pretty good summary?

A. No, I don't think -- again, we do not know what these lists represent. He says he was there in the one letter. I have no idea how to verify whether he's telling the truth or not.

Q. Well, sir, we do know what the lists represent; one is a prospective attendees list and one is an attendees list, right?

A. No. They talk about participants. Being an attendee to a meeting and a participant in

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a meeting are different things.

Q. Is his name on either of those?

A. As I've stated, his name is not on either of the documents.

Q. That's the Colorado School of Mines.

Let's talk a little bit about Professor Lewin. This will be Exhibit 2852.

Dr. Lewin was at NYU, right?

A. That's my understanding. Yes.

Q. And in August of 1972, in August of 1972, Dr. Lewin, who has been retained by the FDA, reports a series of findings of asbestos in different commercial talcs, correct?

A. By X-ray diffraction, yes.

Q. By XRD. Right. That's just to get our bearings. That's August 3rd, 1972.

He reports asbestos in two of 11 of the Johnson & Johnson samples, correct?

A. I believe that's accurate.

Q. Now, XRD, at this time, had a detection limit of about half a percent, correct?

A. Actually with Dr. Lewin's work, I'm not sure. I don't think he ever showed what his detection limit was.

Q. You wouldn't have expected it to be

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less than that, correct?
A. Not less than that, no.
Q. Right.
So even if we have something as low as half a percent detection limit by XRD, asbestos can be present in millions and billions of fibers per gram even at half a percent detection, correct?
A. If it's there, it would just depend on how much is there.
Q. Right.
But you could have millions to billions of fibers per gram and not see it at all at half a percent detection limit?
A. Well, by X-ray diffraction you can't even determine whether something is actually asbestos or not. But if you're talking about from a numerical count, yes, there would be many fibers of asbestos present in a sample which would have a concentration of, let's say, .1 percent.
Q. XRD can detect chrysotile, can't it?
A. No, it cannot. It only can -- it only is able to identify crystal structures, so it can detect whether you have serpentine minerals. There are other serpentine minerals other than chrysotile, so you have to still do further work.

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Q. Serpentine is the class into which chrysotile falls, correct?
A. Mineral group, yes.
Q. Then he issues a final report on 7/31/73, and you and Mr. Dubin talked about his final results, right?
A. I believe we showed some of them, yes.
Q. I want to talk about what happened between those two dates, right, as we dig into the documents. But before that, so this is Exhibit 1297.
Professor Lewin was hired by the FDA to do this work because he was a renowned scientist, right?
A. I'm sorry?
Q. Dr. Lewin was hired by the FDA because he was a renowned scientist?
A. Well, let's just read the language. They state, "The Internationally recognized expert on mineralogical chemistry."
Q. Okay. All right. That's fine.
The FDA says, "I chose Dr. Lewin for this work because he is an Internationally recognized expert on mineralogical chemistry and

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because he is a member of the academic community and therefore, likely to be impartial in a confrontation between industry and Government.
"Furthermore, his competence had previously been recognized by industry by virtue of their own use of him as a consultant which appeared to confer a desirable immunity against possible industry attacks on the validity of the results."
Did I read that right?
A. You did.
Q. Of course, that didn't happen. His results were assailed by Johnson & Johnson and its consultants, correct?
A. And others. But again, you look at, you look at what he was doing and whether it was feasible or not, what he was claiming, and it's not.
Q. Okay. So let's look at some other documents and see what happened.
So he did his first batch of testing by, I'll use a different marker, by XRD, right?
A. He was using powder X-ray diffraction, yes.
Q. This will be Exhibit 3441.
Now, you're aware, sir, are you not, that Johnson & Johnson actually looked at some of

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Lewin's samples on its own internally?
A. I am aware of that.
Q. One of the folks who was at Johnson & Johnson was a fellow named Robert Rolle, and here's -- this is from his files; do you see that, from Robert Rolle or R. Rolle's files?
A. I do.
Q. Do you see, sir, that here's some notes about the Lewin samples of Shower to Shower, and he's dated it August 10, 1972. That's seven days after the FDA first got the report, correct?
A. On that date, yes.
Q. It says, "About one fiber or rod/needle every 500 particles." Correct?
A. You read that correctly.
Q. And that's in the Lewin sample of Shower to Shower, right?
A. Yeah. I mean, the header says, "Lewin samples of Shower to Shower."
Q. And you see it says, "Approximately one-third of these are tremolite"?
A. Of the rods and needles that they're seeing for every 500 particles, yes.
Q. Correct.
And so on 8/10/72, J&J ID's, he says,

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he uses three terms, fibers, rod, needle, tremolite, correct?
A. He says -- I'm sorry. Let's just read it. "One fiber or rod needle every 500 particles."
Q. Right.
A. "One-third of these are tremolite. Two-three rolled talc or talc shards."
Q. So he identified fiber/rod/needle of tremolite?
A. Yes. In this context for quantities.
Q. Now, for us to understand or to characterize how much -- how many tremolite fibers rods or needles that is, we kind of need to have an understanding about what's in a bottle. So he says they identify one every 500 particles.
Now, 99.9 percent of what's in those bottles is talc flakes, right?
A. I've never done those calculations. I don't know.
Q. It's mainly talc?
A. The majority of the mineral in a cosmetic talc is talc, yes.
Q. So as -- now, you're a mineralogist?
A. I a m.

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Q. And a geologist?
A. Kind of the same thing, but yes.
Q. Okay. So if we have one, let's say, 22-ounce bottle, the number of total particles in that bottle is astronomical, right?
A. It would be a very large number of particles, depending on the grind.
Q. Let's say J&J, since that's what we're here for.
A. Um-hum.
Q. That number easily would exceed hundreds of trillions of particles, correct?
A. I've never done the calculation, but it would be a very large number.
Q. I mean, we can agree it would exceed hundreds of trillions of particles, can't we?
A. Again, I would have to do the calculations. These numbers get very big and are hard to visualize. I'd have to make some assumption and do a calculation.
Q. Can we agree it would be trillions of fibers -- I mean trillions of particles?
A. It would be many, many particles. If it's over trillions or hundreds of trillions or even more, I wouldn't know as I sit here today. I'm

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completely guessing.
Q. Let's just, for example, just do something in the middle. Let's say it's ten trillion. Okay?
A. Okay.
Q. Now, if you wanted to say, by in terms of percentage of total particles, right, let's say there was hypothetically, let's say there's asbestos and the asbestos represents .00001. Okay?
A. Percent by weight, not by particle.
Q. Of the particles. We're going to say it's of the particles because we can't do it by weight, can we?
A. You can do it all by weight. Yes. You can do it either way.
Q. Let's do it both ways then. I have my calculator on my phone, so we can do that.
So in terms of total particles, you tell me, you said you haven't done the math. Let's do the math. You tell me what math we have to do.
A. So you want particle by particle count?
Q. Let's do particle first, then we do weight.
A. That's fine. You take your ten

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trillion --
Q. So, let me see. Here, put it up here.
That's ten billion, right?
A. Yes. There you go.
Q. Is that ten trillion?
A. That's ten trillion, yes.
Q. Okay. Then what do I do?
A. I believe you times that by .00 -- do that, four zeros and a one, that gives you, then you would have to convert from the percentage, you have to also divide by another hundred.
Q. Okay.
A. If my math on the fly up here is accurate.
Q. That would be a million particles of asbestos, right?
A. Under your hypothetical, yes, and present at that concentration.
Q. Right.
If there's only a trillion, right?
A. Ten trillion.
Q. If there's only ten trillion.
Now, you said you wanted to do it by weight. How do we do it by weight?

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A. We would just -- well, we have a 22-ounce bottle, you have to take that percentage, would be -- sorry. We have a 22-ounce bottle.
Q. Right.
A. And you are saying we have 0.0001 percent. So you divide 22 by that number again, and I believe you'd still have to correct for the percentage and divide by another hundred -- or, I'm sorry, you'd times by a hundred, I apologize. Math on the fly is always --
Q. That's all right.
22 divided by .00001 equals, and now what do I do?
A. I believe you times it by a hundred to take it out of the percent.
Q. 220 million, correct?
A. Doesn't seem right. We've done something wrong in the math. We can't have more than the starting mass.
Q. You know what, instead of putting you on the spot for math 'cause you are a geologist/mineralogist, not a mathematician, neither am I.
A. I can figure it out, just give me time.

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Q. That's fine. Let's do this, in terms of sheer quantity, it's a lot of asbestos fibers under this hypothetical, correct?
A. I mean, again, it's all in context. You're talking about -- I think we need to time that -- it's not one million 'cause that would also be times by a hundred, so it would be 100 million.
Q. It would be 100 million particles?
A. I believe that's correct. The math is wrong.
But again, you're looking -- so at the end of that calculation, it's 100 million particles out of ten trillion particles.
Q. That's right.
If there's ten trillion particles there, at this concentration you would have 100 million particles?
A. That's correct.
Q. Okay. The reason I wanted to do that is because he's saying about one fiber out of every 500 was a rod or needle and then a third of those would be tremolite, right?
A. That's what he reports.
Q. Meaning, if we did the conversion on that, he would be seeing about one fiber/rod/needle of tremolite every 1500 particles. Is that accurate?

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A. According to these numbers, yes.
Q. So he would be seeing something like one out of every 1500. But if we have trillions and trillions, that adds up, doesn't it?
A. Again, it would depend on how you want to calculate the result, what those numbers would be from a concentration standpoint.
Q. Going back to the Lewin story, this, of course, is an internal document that Johnson & Johnson had regarding his samples, correct?
A. Mr. Rolle, yes.
Q. The next document is Exhibit 2424.
This is going to be August 10, it's dated August 10. It's a summary of an FDA meeting from August 11, 1972. So we have talked about one meeting about a year earlier. That was August 3rd, 1971. Now we're talking about almost exactly a year later, right, if we're in August '72, correct?
A. Correct.
Q. So I'm going to go here to 8/11/72. There's a meeting with FDA.
All right. Sir, do you see that this is a summary of that FDA meeting that took place on

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8/11?
A. I do.
Q. And it says, "The CTFA, FDA and Johnson & Johnson meeting can be summarized as follows." And they give us some context.
"Johnson & Johnson provided hard data showing that Shower to Shower is free of chrysotile asbestos by electron microscopy, X-ray and light microscopy on 15 batches, as well as on the actual sample tested by Lewin.
"Lewin did not agree with McCrone's interpretation of X-ray data; however, he could not satisfactorily explain the absence of chrysotile asbestos fibers in the electron microscopy grids. He said it may be asbestos growing inside the platelets of talc.
"On the basis of our data, CTFA was able to say that the Lewin report is incomplete since it relied only on an X-ray assay which must be confirmed by microscopy." Right?
A. You read that correctly.
Q. So they are saying look, it's got to go confirmed by, and this would be light microscope, correct, optical?
A. They don't specify. The earlier

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paragraph speaks of electron microscopy of the Lewin samples.
Q. We can turn the page and see what it says. Paragraph 7, "Dr. Schaffner" -- who we know is FDA, we've heard his name before -- "asked Dr. Lewin to tell the group what work he proposed to do to confirm his X-ray findings. After some discussion, Dr. Lewin said that to be able to say that a sample contained asbestos, the X-ray results have to be confirmed by light microscopy."
All right? Do you see that?
A. That's what Lewin proposed to do, yes.
Q. That's right.
"If no asbestos tremolite or chrysotile is seen, the sample is declared to be free of asbestos.
"In subsequent discussions, Mr. Ian Stewart pointed out that light microscopy may not detect chrysotile fibers. Dr. Weissler said they recognize that some samples will be passed on that basis, but they are willing to live with that."
First of all, did I read it right?
A. You did.
Q. So what they're doing now is the

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proposal is that he confirm his results, he did it with XRD, this non-microscope, and then confirm it with optical microscopy, right?
A. I don't agree with how you characterized that. Dr. Schaffner asked Dr. Lewin to tell the group what he had proposed to confirm. Dr. Lewin said he would confirm it with light microscopy.
Q. Okay. That's fine. I agree with you.
So Lewin says he'll confirm -- "Lewin to confirm with optical, but a problem is identified with" --
A. Dr. Ian Stewart of McCrone.
Q. By McCrone, right?
A. Correct.
Q. And McCrone says it may not detect the chrysotile fibers, right?
A. That's correct.
Q. Okay. Now, many, in fact, the majority of Lewin's findings were chrysotile, correct?
A. By X-ray diffraction, yes.
Q. This approach was approved by the whole group, wasn't it?

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A. Are you reading something now?
Q. I'm asking -- you've been supplied many, many hundreds of Johnson & Johnson documents, correct?
A. I have. Yes.
Q. And I presume you've gone through them all?
A. I have, the ones that have been given to me.
Q. Okay. Let's just read it together then.
"Dr. Schaffner said that this procedure will be adopted in the proposed policy statement. He asked if anyone present had any toxicological objections to the allowance of one percent weight for weight asbestos in talc. One percent is the limit of detection by X-ray, i.e., a non-detectable asbestos X-ray result may mean up to one percent asbestos being present. No objections were raised."
Did I read that right, first of all?
A. That's correct.
Q. So what they were proceeding with was to verify Lewin with a method that, one, would not see all the chrysotile fibers, correct?

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A. May not see it, yes.
Q. Okay. And no one objected to a one percent allowance of asbestos, including Johnson & Johnson, correct?
A. Again, this was -- I think you're mischaracterizing what is happening here.
May I explain?
Q. Let's see if we could clarify it.
"He asked if anyone present" -- Johnson & Johnson was present, correct?
A. The FDA asked if anybody was present. This is what they proposed to do to resolve the Lewin issue that was presently facing the committee.
Q. I appreciate that.
"He asked if anyone present" -- Johnson & Johnson was present, correct?
A. Um-hum.
Q. Yes?
A. Yes. Sorry.
Q. Sorry.
A. Non-verbal, I apologize.
Q. For Andrea, I'm sorry.
"If anyone present had any toxicological objections to the allowance of one percent by weight asbestos in talc." Right?

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A. That was the question.
Q. "And that a non-detectable XRD or X-ray result may mean up to one percent asbestos is actually present." Correct?
A. That's correct.
Q. Nobody objected, including Johnson & Johnson, correct?
A. That is -- nobody objected, yes.
Q. And it says that "Dr. Lewin promised to complete his confirmatory phase 43 samples by October 1st." Right?
A. That's what it states.
Q. Now, the optical that Ian Stewart, who at the time was Johnson & Johnson's consultant, right?
A. That's correct.
Q. He said optical won't find the chrysotile, correct?
A. May not find the finest fibers of chrysotile, yes.
Q. And so when he issued his final report, the optical did not confirm the chrysotile, did it?
A. That is, nobody found any chrysotile in the samples by optical microscopy, true.

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Q. He confirmed a result using a method that they knew might not see the chrysotile, correct?
A. No. That's incorrect. There's issues of sometimes when you have very small chrysotile fibers, PLM will not be able to resolve them. That is the concern raised by Ian Stewart of Walter McCrone.
Q. Right.
Ian Stewart said it might not see all the chrysotile present, correct?
A. Correct.
Q. That method is what Lewin used to, quote, unquote, confirm his previous findings, correct?
A. That is what Lewin proposed to do, and the FDA agreed to it and told him to do it.
Q. Now, another document -- let's see here. Before I move on from Lewin, which I'm about to do, some of the documents you went through yesterday talked about some of Johnson & Johnson's consultants. There was Buerger, is it B-e-u --
A. B-u-e-r-g-e-r.
Q. Buerger, M.I.T. He did XRD, right?
A. That's correct.

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Q. Which is, at least according to that meeting minutes from August 11, '72, that was good to about one percent, right?
A. Well, what Lewin was doing he said was down to one percent. Buerger may have had a lower detection limit.
Q. May have. Do you know what it was?
A. I'd have to review his report if it's in there or not.
Q. In all fairness, just us talking here, it's probably between half a percent and one percent; is it not, sir?
A. It can get down to .1 depending on the instrumentation and how it's run. But the lowest you could probably get it with what they were doing back then was .01.
Q. Do you know what --
A. 0.1, I apologize.
Q. Do you know what his sensitivity was?
A. I'm not sure. I'd have to --
Q. Whether it was --
A. -- whether he reported or not.
Q. -- one or .1?
A. Again, I'd have to review. That's all I'm saying.

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Q. I'm going to put a question mark.
The next guy was Brown at Princeton, and he did XRD as well, right?
A. That's correct.
Q. Then there was Colorado School of Mines, and they did XRD, correct?
A. In part, yes.
Q. Then there was Carnegie, and they did XRD, right?
A. That's correct.
Q. And then there was Pooley. He did a few things, including electron microscopy, right?
A. Correct.
Q. And then there was McCrone, who did a few things, including TEM, right?
A. Correct.
Q. Now, we did this hypothetical, you and I, where we said, and this is just assuming, just assuming there's only ten trillion in a bottle and it's present at .00 -- 00001, right, XRD, it would be negative, negative, negative, negative. Correct?
A. If that was the actual situation.
Q. Okay. XRD is still the first step of Johnson & Johnson's biweekly testing for its talc,

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isn't it?
A. No, it is not.
Q. Johnson & Johnson uses J4-1, correct?
A. Not for the testing we do for them. We follow the current U.S.P., but we do mandatory microscopy. We don't rely upon the results of powder X-ray diffraction.
Q. Right.
We're talking about their actual testing frequency. Okay?
A. Yes.
MR. PANATIER: I'm sorry?
MR. DUBIN: We're having trouble hearing.
A. Okay.
THE COURT: Even with the microphone, you do have to speak up.
A. I'll bring it closer. Hopefully that helps.
MR. MAIMON: If he wants to put it on the ledge, it would be higher.
THE COURT: Try the ledge. Let's see how that works.
Thank you.
BY MR. PANATIER:

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Q. So now you actually, you have a large number of children, don't you?
A. I have children, yes.
Q. Just speak like you're trying to get them to dinner. Okay? All right.
Now, let's talk about J4-1. Okay? J4-1 was the industry test adopted in about 1977, correct, or '76?
A. In conjunction with the FDA, but yes, it was the industry standard at that time.
Q. Okay. And the way that worked, quite simply, is an XRD test is done, right?
A. I described this in my direct. Yes.
Q. Okay. If XRD finds nothing, nothing further is done, right?
A. If you are following the method exactly, yes.
Q. If it finds something, then you do optical or light microscope, correct?
A. That is correct.
Q. Okay. There is no TEM in J4-1, correct?
A. That is correct.
Q. Okay. And so they actually describe a .5 detection limit, correct?

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A. I think the requirement is you have to at least get to .5 to be able to run the method as stated, yes.
Q. So if XRD doesn't pick up the presence of one of the minerals that can constitute asbestos, under that method you stop and you sell the talc, correct?
A. If you follow that method explicitly, yes.
Q. Only if you pick it up at greater than half a percent or thereabouts do you go and do optical microscopy, correct?
A. That's correct.
Q. And the method is only for amphibole, correct?
A. As written, yes.
Q. Not chrysotile, correct?
A. That is correct.
Q. Let's chat about this document that you discussed yesterday with Mr. Dubin. Here you go, sir. And this is exhibit -- I don't know what exhibit this is. Here you go. But it's in evidence.
It's dated August 6, 1971. And interestingly, that's the same day that

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Mr. Pattengill wrote to Johnson & Johnson saying that he remembered that all those results were contamination.
Do you recall that?
A. That's not what he said. He reported that based upon him attending the FDA meeting, he had reason to question what he had -- what had been reported. And then he went back, it appears, and tried to -- investigated that and reported to Johnson & Johnson.
Q. Three days after the meeting, he said he remembered it, right?
A. No. He says from attending the meeting, something happened at the meeting that made him think of that as a possibility, I am assuming. But he attended the meeting, obtained some information, went back to check some of his reports and thought there was an issue and reported it.
Q. Is it reasonable to think that what made him think about this, maybe it was contamination all of a sudden, is that Mr. Caneer was reporting clean fibers to the FDA?
A. I can't draw those -- I have no idea what was said at that meeting and what was meant by clean fiber in the FDA meeting minutes.

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Q. You talked about this document from August 6, '71.
A. Yes.
Q. Where Mr. Ashton says, "I have checked into the mineralization of that part of the territory"?
A. Correct.
Q. You recall that?
A. I do.
Q. And he said that the minerals included, you know, a number of things, but there's chrysotile, tremolite and actinolite, right?
A. Yes.
Q. Okay. And he's talking about shipping a drum from the Crosetto mine in the Chisone Valley of the Italian Alps, right?
A. That's what it states.
Q. Now, the Johnson & Johnson mine that they actually got their talc from is called the Fontaine or the Fontana mine, correct?
A. It can be called that. Yes.
Q. Okay. And, sir, did you say something about does this have anything to do with Fontana yesterday?
A. Mr. Dubin said that.

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Q. Yeah. I think you agreed with him, didn't you?
A. No. I've reviewed my testimony, but where Crosetto is and Fontana, they're across the valley. Those are both located at Val Germanasca.
I made the distinction, I believe, when I answered Mr. Dubin's question, that Val Chisone is a different valley where the mills are located. The actual mines are all up in Val Chisone. Both Crosetto area and in the Fontana area.
Q. Right.
So this would be the talc that they are talking about putting into their baby powder, correct?
A. Possibly, assuming they were getting it from the Crosetto side. The records appear to be they were getting it from the other side of the valley, but it potentially could be.
Q. It's the same overall geological deposit, isn't it?
A. Yes. You literally have this, you have like a fold of a talc body in there and then the mountains have gone up and then erosion has cut out the center part.

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Q. Let's talk about Dr. Langer. And I only have a couple documents for Dr. Langer. This one will be Exhibit 2374.
So Dr. Langer, the story you told about Dr. Langer was that Dr. Langer had said he found asbestos and then unsaid he found asbestos basically, right?
A. No. I think his article said he may have been mistaken. He actually didn't do the analytical work necessary to conclude that he had found asbestos.
Q. Okay. Tell me if this sounds right as to what the story was.
Initially they had a preliminary report that said five to 25 percent asbestos. He said that was incorrect, that was preliminary. Correct?
A. The numbers escape me exact, but I'll take your representation.
Q. All right. That doesn't sound like it's incorrect, does it?
A. No, it doesn't.
Q. He always maintained there was trace asbestos. And, by the way, when we talk about these numbers of .00001, that's scientifically, you call

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that trace or sub trace, correct?
A. It really depends. Usually you report out something as trace that's below your detection limit. So depending on the methodology you are using would define what you're meaning by trace.
Q. Okay. So it differs from scientist to scientist?
A. No. It would differ between the testing being done. For example, if you were performing X-ray diffraction and there was an amphibole in there that was below your limit of detection, you could report it out as trace. Or you lower your ability to quantify it, you would be trace.
If you're doing TEM, a concentration below your ability to quantify it would be a trace amount. You wouldn't be able to give any number to it. So you just report it as trace, meaning it's less than your detection limit with the methodology.
Q. Meaning you identify it there, but based on your methodology you can't quantify it. Correct?
A. That is one way to use trace, yes.
Q. So this is from, you should have

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this, this is a Johnson & Johnson note, and it's a report of a call from June 19, and I'll represent this is 1972. Okay?

"Dr. Langer, Mount Sinai School of Medicine, called just before lunch. He has a favor to ask. Would Dr. Nashed please have sent to him a sample of sodium sesquicitrate. He has been trying to get a sample for some time and has not been successful."

That is not important. Here's what's important. Down here. Right here.

2:30 p.m., "Dr. Nashed called. I gave message and he questioned: Would it be to our interest to have a comparison of sodium sesquicitrate and chrysotile? Would it get Dr. Langer away from insisting that he believes we may have trace amounts of asbestos in our talc? He said, Call Dr. Rolle."

See that?

A. I do.

Q. "Called Dr. Rolle. He said he didn't see any harm in sending it to Langer, but he feels that Langer is not going to retract his statement and as a scientist, will stick by his feeling that there may be traces of asbestos in our talc."

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Right?

A. You read that correctly.

Q. At least as of June 1972, he's saying there's traces of asbestos in talc, correct?

A. That's not what he's saying. This is what Dr. Rolle thinks is that he will say.

Q. The Johnson & Johnson person reported this in this memo, correct?

A. Yes. He says he feels, meaning Dr. Rolle feels, that Dr. Langer is not going to retract his statement.

Q. Okay. Well, that's fine. I think we have some information directly from Dr. Langer. So that was 6/19/71. The next exhibit is 2382. I'll just show you this one.

A. Thank you.

Q. Okay. Sir, do you see that this is a memo of a meeting with Dr. Langer about three weeks later on July 9?

A. That's correct.

Q. It says, "Meeting with Dr. Langer on July 9 concerning analytical analysis of talc." Right?

A. Correct.

Q. They actually met with the guy; true?

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A. They met with him on numerous occasions, but yes.

Q. If you turn to the third page, "light and electron microscopy of Johnson's Baby Powder."

Do you see that?

A. I do.

Q. "Langer demonstrated his technique for observing fibrous minerals in Johnson's Baby Powder." And it talks about his process.

"After examining the sample in the light microscope for a short time, he stated that he could pick up some non-plate particles that could be amphiboles or other asbestos forms or fibrous talc or in my opinion," that's the Johnson & Johnson writer, "talc fragments."

Now, that's light microscope, right?

A. That's correct.

Q. He said, "He estimates the amount in the sample to be on the order of one or two percent."

Let's go down to electron. "Using electron microscopy, Dr. Langer has demonstrated to me the presence of some very fine fibers at moderately high magnification which he identifies as chrysotile asbestos." Correct?

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A. You read that correctly.

Q. So this is three weeks later he shows them what he was talking about in the previous phone call, correct?

A. He shows what he believes is the chrysotile that he's seeing, yes.

Q. All right. He's at Mount Sinai, right?

A. That's correct.

Q. This next one is Plaintiffs' 2403. He actually writes them a letter, doesn't he, later that year? Actually, this was the year before.

A. This is from 1971. Yes.

Q. November 10, '71, he actually wrote them a letter; true?

A. Correct.

Q. You see this is from Mount Sinai?

A. I do.

Q. To Gavin Hildick-Smith?

A. Yes.

Q. At J&J, right?

A. Correct.

Q. He says that "Electron diffraction" -- meaning he's doing electron microscopy, correct?

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A. Yes.
Q. "Electron diffraction on these grains again yield the grains -- again yields a talc pattern which is very definitely defined -- well-defined hexagonal array of spots. We also observed trace amounts of chrysotile asbestos only when the talc was sonified and markedly dispersed."
Sonified just means that, as far as my understanding is, you put it in a solution and then you use a sonicator, which is a very, very rapidly vibrating pad, and you stick it on there and it goes "bzzz," and it disperses everything inside that tube, correct?
A. That's one type of sonication device.
Q. So anyway, he writes them and says they identify chrysotile asbestos, correct?
A. After the sonication, yes.
Q. It says, "The amounts are relatively small occurring in amounts we estimate at less than .01 percent." He says, "The J&J baby talc is of quite high quality and as a matter of fact, in relation to the number of samples we have examined thus far, it is the purest." Right?
A. That's what he states.
Q. Still contains asbestos, right?

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A. That's what he's reporting here, yes.
Q. So this is the third communication from Dr. Langer that you and I have discussed where he reaffirms the presence of asbestos; true?
A. I don't think it's reaffirming anything. We're talking about an original report here versus subsequent work that was being done.
Q. Well, one time he writes a letter where he said he did work, found it, right?
A. In '71, yes.
Q. Then in '72 they call him and he reiterates it's there, correct?
A. No. No. Dr. Rolle, they were calling Dr. Rolle to see if it was worth sending him the sodium sesquihydrate. Sodium sesquihydrate has a very similar appearance to chrysotile. That was an issue back then.
And so the discussion was whether sending the sodium sesquihydrate to Langer would be good for him to be able to look at that material and see if it was the same as the material he was seeing in the powders that he was calling chrysotile.
Dr. Rolle said that he wouldn't, he didn't know what would happen, he would thought that Dr. Langer would stand by what he said.

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Q. And he said I don't see any issue in --
A. Sending him the sodium sesquihydrate so he could look at that, yes.
Q. Then three weeks later they're in Langer's lab and they're looking at it and he says here's the chrysotile?
A. They're looking at it, but again, if you read the memo, they're not doing the diffraction work. It's simply again looking at the morphology of the particles.
Which is important about the sodium sesquihydrate because again, it has an appearance similar to chrysotile. So if you're only looking at the appearance of the particles, that is an interference.
Q. You didn't ever look at any of these particles, this is just your speculation as to what could have happened, correct?
A. It is my interpretation of looking at the documents and the records. The sodium sesquihydrate was known to be an interference of chrysotile in creating very thin, tubular-like fibers. So there was concern when you're not doing the diffraction, which Langer was not doing in the

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'72, he was simply looking for tubular fibers.
So again, if you're not doing your analytical work to the rigor necessary, you cannot conclude that you have something. Langer's results are incomplete. They're not scientifically reliable.
Q. Sir, you never looked at a single one of his samples, have you?
A. That has nothing to do with it, sir. I am looking at the record. We are talking about the record of what he was doing to make these findings. His analytical procedures, what he says he was doing is incapable of drawing those conclusions scientifically.
Q. We'll see what he says because he's talked about this, okay, which we'll get to.
This is from June 17, 1972. And this is a memo to file by, I believe it's, yeah, Nashed.
THE COURT: What's the marking on that, please?
MR. PANATIER: This one is 2364, your Honor.
THE COURT: Thank you.
BY MR. PANATIER:
Q. Here's a copy.

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Top of page 2. "I asked Langer if he can state that our baby powder is free of asbestos as a result of the conference and review of August 3rd, 1971, with the FDA. He said he still thinks Johnson & Johnson's product contains minute traces of asbestos and he believes he can find asbestos fibers after breaking down the platelets with ultrasonic energy." Correct?

A. That's correct.

Q. That's June '72.

Sir, you know that as recently as last year he reaffirmed what he did at Mount Sinai, correct?

A. I don't know that.

MR. DUBIN: I object.

MR. PANATIER: It's in evidence.

THE COURT: Sidebar.

(Sidebar.)

MR. DUBIN: Just for the record --

THE COURT: Well, now I'm here.

MR. DUBIN: We're now talking about whatever Dr. Langer said in the New York Times article that post-dates historical documents that we've been discussing during a time period when, for example, Dr. Sanchez has done all the testing work,

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advised the company about what he has and has not found back in the 1970s. I'm not permitted to get into a long with the fact that I'm not allowed to get into real changes and things that their experts have said. And I think this is far afield from what I was allowed to ask Dr. Sanchez about, which was the historical record of these documents. So I would object with this witness.

MR. PANATIER: He asked him, they went completely over Langer, and they said that we had misrepresented Langer's findings on the boards. And he said we have to dig into the documents. That's what I'm doing.

THE COURT: I'll allow it.

Before we leave, Ercilyn notified me that she can hear your conversations. I -- the official record cannot have that. So if you need to get closer --

MR. DUBIN: Okay. I'm just trying to gather all the documents.

THE COURT: I know. The voices that I'm concerned about, I don't want your discussions to be on the record.

MR. DUBIN: Okay. No problem.

THE COURT: Take a break at 10:30.

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MR. PANATIER: Yeah.

(Sidebar ends.)

BY MR. PANATIER:

Q. All right. So this is the last Langer thing we're going to look at. I'll just let you see it.

You see this is an article from The New York Times from December 14, 2018?

A. Okay.

Q. Go ahead and turn to the next page. Just take a look at that excerpt and then I'll ask you some questions about it.

MS. BROWN: Counsel, we have a copy.

MR. PANATIER: That's fine. Hold onto that one then, Dr. Sanchez.

BY MR. PANATIER:

Q. Now, assume nothing from the blackout. Sometimes courts, we have to do this for different reasons. Okay?

But you see this is from The New York Times, we don't know the title, but from December 14, 2018?

Do you see that?

A. I do.

Q. Okay. And there's a quote from

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Dr. Langer. "In a recent interview, Dr. Langer -- Mr. Langer told the times that Dr. Chalmers spoke for himself and for the institution, not our research group. He reiterated that his team had detected asbestos in Johnson's Baby Powder. I stand by that today, absolutely," he said.

Now, did I read that right?

A. You did.

Q. Is that the first time you've seen that?

A. I don't know if I've seen this or not before with all the redactions. I'm sorry.

Q. Sir, you're aware -- you talked about the FDA. You're aware, in approximately '73 or '74, the FDA found approximately 107,000 fibers per gram of tremolite in Johnson's Shower to Shower, correct?

A. I've seen an internal document from the FDA using an optical technique reporting that, yes.

Q. When you were talking about Dr. Pooley -- maybe I'll come back to that. I don't know it's that important.

Okay. We will do this one. This will be Exhibit 2049. It's Argonaut.

Johnson & Johnson was aware, sir,

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that both its Hammondsville ore body and its Argonaut ore body contained levels of chrysotile asbestos by virtue of their own core sampling, correct?
A. In certain areas, yes.
Q. This is Exhibit 2049. The jury has seen this. "Examination of talc samples from the ore body." And all I want to do is look at some of these percentages.
First of all, they took core samples, 38 core samples, right?
A. Correct. This is discussing the Argonaut ore body, yes.
Q. Right.
But they also compared it to three then current which are listed here at the very bottom of Table 1.
A. Current.
Q. Have you reviewed this before, sir?
A. I have. Yes.
Q. Okay. If you go under the summary on the first printed page --
A. I'm there.
Q. -- do you see at the end of the first comparison they say, "For comparison, three core

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samples from the current ore body were also examined"?
A. Correct. Again, this is all Argonaut, but yes.
Q. No, the current ore body then was Hammondsville. Argonaut was not yet approved until '76.
A. Not approved for baby powder production, yes.
Q. Not approved for anything, sir.
A. I'd have to check the records for that.
Q. Okay. You don't know, do you?
A. Not with specificity. But whether or not it was being used for other purposes, I believe it was, but I would have to review the records since you're challenging me --
Q. I'll just ask you: I asked Dr. Hopkins in this case, the jury has seen this, that Argonaut was first approved in 1976.
Do you disagree with that?
A. I would have to look at the context.
Q. Here's all I want to ask you about is they say that only one exceeded .0005 percent, right?

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A. Correct.
Q. Okay. So when we go back to our math, what they said was they had one that exceeded .0005 percent, which in a matter of percentage is greater than .00001 percent, correct?
A. Correct.
Q. And they had 15 where they found chrysotile asbestos, right, in the 38 core samples for Argonaut; true?
A. Is that what they said? Hold on. Give me a second to check that.
Correct. They said 15 samples that did show an asbestiform mineral, only one exceeded the estimated level.
Q. Chrysotile, if you find chrysotile, that's asbestos; there's no dispute?
A. If it's been identified correctly, yes.
Q. If you go to Table 1, they did X-ray diffraction, right?
A. Correct.
Q. XRD is that one that has something like one percent detection limit, half a percent maybe down to .1, right?
A. Somewhere in that range, yes.

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Q. And they didn't find any asbestiform minerals using XRD. It's all over here. Non-detect. One maybe chrysotile, correct?
A. That's correct.
Q. But, and actually Moshe just pointed out to me, which he does sometimes, that they actually state what their detection limit was in here, so we don't have to speculate.
A. Oh, for the X-ray diffraction? Good.
Q. Yeah, for the XRD.
Here we go. "By XRD, in no instance was any asbestos or potentially asbestiform mineral identified by XRD, the limit of whose sensitivity is between half and one percent for amphibole and probably slightly higher for this chrysotile asbestos." Right?
A. You read that correctly.
Q. So when they get all those non-detects, that's only credible down to about one percent or so, at least in this report, right?
A. Yes. Of course. Any time you analyze something, it's always within the scope of what that analysis can tell you.
Q. Right.
When you are using a more powerful

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tool like electron microscopy, that's when they actually got the hits for chrysotile and they also found amphibole, correct?

A. They do report both chrysotile and amphibole detections.

Q. All right.

MR. PANATIER: Your Honor, good time for a break?

THE COURT: Yes.

Members of the jury, we'll take the morning break now. 15 minutes. Leave your notebooks here.

Remember my instructions: Do not discuss this case, including the testimony you've just heard. No research of any kind whatsoever.

You may choose either all to stay up here in the jury room or to go downstairs. You just need to be in agreement.

All right. So be ready to come back up at quarter of. Thank you. Enjoy.

(Jury exits.)

THE COURT: Thank you, Dr. Sanchez. You can step down.

Thanks, everyone. Quarter of.

(Recess: 10:29 a.m. to 10:46 a m.)

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COURT OFFICER: Jury entering.

(Jury enters.)

THE COURT: Please be seated. Make sure cell phones are turned off.

Mr. Panatier, whenever you're ready.

MR. PANATIER: Thank you, your Honor.

BY MR. PANATIER:

Q. Dr. Sanchez, I just wanted to make sure I understood what you said. Were you saying that Dr. Langer was not getting diffraction patterns on what he was looking at?

A. Depending on the -- I'm sorry, excuse me. When you look at the specific document, there was one from '72 which was notes from somebody from Johnson & Johnson going to go meet with him.

Q. Okay.

A. And that description, no, he was simply looking at the external, the morphology of the particles. He was not doing diffraction work.

Q. Okay. So I just wanted to be clear. Do you still have the letter that he sent them in '71?

A. That's not what I was thinking.

Q. I understand.

A. That's fine.

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So I do have it up here. What is the date on that one?

Q. That's November 10, '71.

THE COURT: For the record, what's the exhibit number?

MR. PANATIER: 2403.

THE COURT: Thank you.

BY MR. PANATIER:

Q. And he very clearly is using electron diffraction; he is getting patterns in this letter, correct?

A. In that letter, yes. It was the other letter I was speaking to.

Q. One of my items got out of order, so I just wanted to ask you about it real fast. We talked about some pamphlets that your company had distributed for the Defense Research Institute.

This will be Exhibit S-5.

(S-5 was marked for identification.)

BY MR. PANATIER:

Q. Sir, you see this is a newsletter from the American Industrial Hygiene Association?

A. I see that.

Q. You've seen this before, correct?

A. I've been shown this before, yes.

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Q. And so it's a newsletter. If we go to the second page, who's that guy?

A. We've already seen that photo of me.

Q. Okay. And it says, "As an industrial forensics laboratory, we go beyond data delivery. We provide solutions." Right?

A. That's what it states.

Q. So this is connect with an expert, right?

A. That's what it states.

Q. Do you get residuals for any of these, for anything?

A. I don't know what that means.

Q. I was making a joke. You know when stuff gets published, do you get -- never mind. I'm not very funny.

A. No. I have no part in our marketing efforts in the company and how they use my image.

Q. Another document you talked about, and this is Plaintiffs' Exhibit 2363 in evidence.

Here you go, your Honor.

Do you recall discussing the Baby-Mate entry on the boards?

A. I do.

Q. And Mr. Dubin said that's not even

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Johnson & Johnson, right?
A. That's correct.
Q. Let's see what they say. Okay. January 30, '67. Baby-Mate powder. They are investigating the Baby-Mate powder, correct?
A. It appears so.
Q. It says that "The talc base used in this product is better than 97 percent pure talc. The remainder is associated with carbonate and less than half a percent of fibrous -- of the fibrous tremolite."
Right? So they're saying it's fibers of tremolite, correct?
A. They report fibrous tremolite, yes.
Q. And that means fibers of tremolite?
A. Correct.
Q. Okay. "This about compares with Italian Number 1 talc and is slightly less pure chemically than Ental EXTRA talc."
Now, earlier today you brought up Italian Number 1. Italian Number 1 was the talc used by Johnson & Johnson, correct?
A. I believe that is one of the names for it. Yes.
Q. So it says this about compares with

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the Italian talc that Johnson & Johnson was using, right?
A. That's what it states.
Q. And, in fact, they say, they're trying to determine the talc source and they say, "The structure of the particles, however, and the presence of the associated carbonates and tremolite lead me to believe this is an Italian talc, Robert Russell." Right?
A. That's what it states.
Q. So that would be the relation to Johnson's Baby Powder, wouldn't it; they're using Italian talc, correct?
A. Again, what it says here, this guy doesn't know, he believes it may be an Italian talc. That's not saying it's Italian talc. We don't know what the source of Baby-Mate is.
Q. But what he is saying is the percentage of fibrous tremolite, he says this about compares with Italian Number 1 talc which they were using, right?
A. I think overall, that's what he says here.
Q. Okay. Now, you also serve as an expert witness, or have in the past, for Imerys,

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correct?
A. In the past, yes.
Q. Imerys is the supplier of the raw talc and has been since 19 -- about 1989, 1990, to Johnson & Johnson?
A. In one of its entity firms.
Q. Right.
It's been called Luzenac, it's been called Rio Tinto and so forth, right?
A. Those are some -- some of the names, yes.
Q. All right. Let me give you, this is Exhibit 3695-247.
MR. DUBIN: We're going to have to approach about this.
THE COURT: Sure.
(Sidebar.)
MR. DUBIN: This appears we're going to be cross-examining Dr. Sanchez with Imerys documents.
At this phase of the trial, your Honor, the issue is what Johnson & Johnson should have known and understood. The cross-examining him with Imerys documents in a case with state of mind, I think, is improper.

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You've looked at this Imerys document, does that inform how you reviewed that document, then he would have to also rely on all the testing he personally has done because that similarly would inform how he read these documents. We've kept it to J&J notice issues. I think that's where it should be.
MR. PANATIER: This is their supplier. Known or should have known, they asked the supplier, this is what they get. That's pretty clear.
And this is -- I have two documents, or three, I have three. I have this one which covers Argonaut, still in Argonaut. Then I have two Chinese. And he's an expert for them and he's seen all of this. If he wants to try and say he hasn't seen it, that's fine, but he's seen all of it.
And, again, counsel brought up all of the Chinese. He said we never had a positive result. But on knew or should have known, I think it's a pretty -- it's not attenuated to say if you ask your supplier, here's what you get.
THE COURT: Thank you.
Anything further?
MR. DUBIN: Yes, your Honor. Then,

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again, if he's permitted to go into this area and wants to cross, the ideal is what he should be and what should he (inaudible) looked at the products themselves and (inaudible) asbestos and how is it not relevant that (inaudible) he would have told us there's no asbestos.

So I feel like it's part and parcel, we're getting far afield from what Johnson & Johnson's state of mind.

MR. PANATIER: One is regular testing. The other is litigation testing. Quite clear there's a delineation. Yesterday we got into the regular routine testing with Dr. Sanchez and this is the regular routine testing.

THE COURT: Since Imerys or one of its predecessors was a Johnson & Johnson supplier and due to the fact that this is what Johnson & Johnson either knew or should have known, this is permissible cross-examination and I will allow it.

MR. DUBIN: Will I be allowed to then ask this doctor about his own testing, how that relates to what he understands Johnson & Johnson should have known?

THE COURT: No. I mean, this is now about the conduct of Johnson & Johnson. This is

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about the disclosures that were made on his report. This does not open the door now to anything that was not within his report that is proper at this phase.

MR. DUBIN: I'm sorry, I understand. I'll sit down. I just wanted to ask about that.

THE COURT: Sure.

MR. DUBIN: Obviously his testing is in his report. We do think it's within the scope of (inaudible) is aware historical documents (inaudible). We'll make that proffer again. I understand the court's ruling, so I can't do that but I do want to make that proffer formally, but we believe that's responsive to those issues.

THE COURT: Thank you.

Anything on that issue?

Thank you. Let's continue.

(Sidebar ends.)

BY MR. PANATIER:

Q. All right. Have you had a chance to look at that?

A. I have.

Q. And you have reviewed that, as well as probably thousands of Imerys documents? We have a very long list you've been given.

A. If this is a part of that list, then

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yes, I have reviewed this.

Q. This is Exhibit 3695, and you could see that this is a summary of some testing that Imerys did, correct?

A. That's correct.

Q. And you understand that Grade 66 is the domestic baby powder powder and Grade 96 is what they were selling to Canada, correct?

A. From the Vermont source, yes.

Q. Right.

It's the same source, it just was going International, Canada, right?

A. I'm foggy on the details as I sit here today. I can't verify that.

Q. That's fine. Let's look at their results. Chrysotile structures, you see that this is the quarterly testing, right?

A. For this time period, yes.

Q. Okay. And you can see here that they have one, two, three, four positive results for chrysotile, correct?

A. Correct. Observations of one fiber.

Q. And this is by transmission electron microscopy, they're looking at that super teeny tiny amount of talc, right?

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A. That's correct.

Q. And the analyst here has calculated what the concentration would be of structures per gram, correct?

A. That's correct.

Q. So just by finding one chrysotile fiber here, that equates to, it's expressed in terms of less than 132 million structures per gram, correct?

A. Ten to the sixth. I believe that's accurate.

Q. Okay. So when they find one here in 2002, that's approximately 133 million fibers per gram, correct?

A. No. It's less than 100 -- this is one of those, in the noise of the measurement, but again, they are reporting out their -- the concentration that they can quantify to by -- with the data and the method they're using is 133 million structures per gram. What they're observing is less than that.

Q. Okay. Well, I think this might help us. Look in the ones where they don't find anything, right. They don't see any fibers there?

A. Correct.

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Q. Their analytical sensitivity is 80 million fibers per gram, correct?
A. Well, again, you're calling this analytical sensitivity. I believe this is a detection limit, which is based upon a Poisson distribution over the observed count.
Q. Right.
A. So the upper limit of your Poisson would always -- would vary when you're in that insignificant value.
Q. What this means is when they find zero, all they can say is if it's present, it's present at less than 80 million structures per gram, correct?
A. They can't even say it's present. They're saying this test certifies there is no chrysotile detected or asbestos detected above that detection limit.
Q. That's right.
A. That's all it says.
Q. That's right.
And the inverse is true, it's also pointing out to say that it cannot draw conclusions below 80 million structures per gram, correct?
A. Exactly. You cannot draw any

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conclusion about what's in there below the method by the test.
Q. Right.
Because if you don't have an analytical sensitivity or detection limit that goes below 80 million structures per gram, you cannot draw conclusions one way or another as to what might be in that concentration?
A. It would be improper to draw any conclusion over what's there because you have no information to say it's there.
Q. I gotcha.
But then we have these positives, one, two, three and four, and there you can see the concentration per gram jumps, doesn't it?
A. In this example, yes.
Q. And this would be saying, look, there's something up to 132 million structures per gram, correct?
A. No, it's saying the same thing. Whatever they're calculating here, I don't know. I need to see the full report. But whatever they're calculating here, whether it's a -- appears to be a detection limit to me, their detection limit is what it is for the method based upon what the method

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states how you calculate that. All they're saying is whatever they observed in there, it's less than that value.
Q. Okay. So they don't say what it exactly is, do they?
A. They can't say what exactly it is. The measurement is -- it's an insignificant measurement. You cannot take insignificant information and calculate out concentrations from it.
Q. We know that in these tests they're looking at, they're looking at some millionth fraction of a gram, aren't they?
A. By nature of the TEM, that's just -- there's no other way of doing it by TEM.
Q. That's right.
So they're only looking at, let's just say, to make it easy, a millionth of a gram, and in looking at a millionth of a gram they find one fiber, right?
A. No. Well, this is what they're reporting based upon their analytical data. Whatever that is, we don't have in front of us, so I'd hate to characterize it as a millionth of a gram without more information.

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But again, this is based on their analysis, they saw one chrysotile structure less than five microns in length. That's all this is telling me here, which is below their detection limit of their methodology. It's in the noise of the method, of the analytical technique.
Q. They found asbestos four times, correct?
A. They found one particle which they can't quantify and it's within the noise of the analysis and they report it out.
Q. And we may actually go and look at how much they were looking at, but if they're only looking at one millionth of a gram, right, and if it's a homogenized sample, then what you can say is if they're looking at one millionth of a gram, that there have to be a million fibers there for them to see one, correct?
A. In the gram of talc, yes.
Q. That's right.
A. It's always with the, it's just a way to calculate concentrations and you need to look at it in context of the full concentration calculation.
Q. Pretty simply, if you're looking at a millionth of a gram, there have to be a million

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present for you to see one?
A. I don't think that's accurate.
Q. That's what you just said.
A. No, that's not what I said. I disagreed with your characterization there.
The issue is you look at the detection, what that is. That detection there is, what was it, 132 million fibers per gram, based on the data they did for their analysis.
Q. Um-hum.
A. That's saying for every gram of talc, that's their analytical sensitivity. It would be less than whatever that 133 million would be. I don't think that's what you said.
Q. What I was saying pretty simply is, if you look at, if you have a homogenized sample, meaning everything is evenly distributed, and you take one millionth of that sample and you find one fiber, then scientifically you can say in order to find that one fiber in a homogenized sample and I only look at one million, there need to be a million evenly distributed, correct?
A. No, because again, you're confusing particle counts with masses. So again, it doesn't work that way.

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Q. I'm not, I'm asking you particle counts.
A. No. These reports -- the idea of it being in there in a gram of talc, we still have that mass component. So again, it depends on how -- there's all sorts of ways you can calculate these. We're getting lost in different ways to calculate the same type of data.
Q. Okay. I'm asking you to do -- by the way, the ASTM D-5756 that you have utilized, the one that did not become validated, remember that?
A. That's not accurate. It was not -- they didn't have validated information, so they withdrew it.
Q. Okay. Fine.
That was a mass concentration method, right?
A. Yes. You would take your fiber counts and then assign masses based on the size of the particles and do a weight percent calculation.
Q. And then there's D-5755, which is a particle structure per gram?
A. Correct. You do the same approach. It's just how you treat the end data.
Q. There's one way is to say there's

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this much asbestos by weight and there's one way to say there's this much asbestos by particles?
A. No. Particles by gram. There's still a mass component to that calculation.
Q. Right.
It's how many particles in a gram, right?
A. Correct.
Q. As opposed to how much asbestos weight there is per gram, correct?
A. Again, yes, a weight percent would be mass by mass. Fibers per gram would be a particle count per gram.
Q. This is Exhibit 3695-253. This is another Imerys document.
MR. DUBIN: Same objection.
THE COURT: Noted. Overruled.
BY MR. PANATIER:
Q. Can you see here, sir, Guangxi; this is China now, right?
A. That's correct.
Q. And do you see here that under chrysotile structures there's another hit in January 2003?
A. I see that.

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Q. Okay. Then if you go to the very next page, at the bottom, there's another hit for chrysotile asbestos in November 2001, right?
A. I see that.
Q. Guangxi is where Johnson & Johnson gets its talc, correct?
A. Yes, for the U.S. market, yes.
Q. All right. And then the last one of these reports that we'll look at, sir, here, your Honor, here you go, sir, this is 3695-252. And this is a duplicate, just so we're clear, you see there's right here, 3199-2?
A. I see that.
Q. And then the one I just handed you has 3199-2?
A. I see that.
Q. That has the finding of the number of structures, right?
A. Correct.
Q. The reason I'm giving you that is because this one actually provides us with the count sheet. And if you go to the very last page, that's the one for the positive where they got 3199-2 and they found the one structure, correct?
A. Okay.

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Q. Do you see that?
A. I do.
Q. First of all, we know the length and width of this fiber, this fiber is, what is that, 14-to-1?
A. It's .7 by .05. I think I would do that on a calculator to make sure that was right.
Q. Okay. That's fine.
A. I think you're right, but just to make sure.
Q. 14.
A. Thank you.
Q. Here the analyst tells us, again, the structure concentration in terms of structures per gram, correct?
A. Where are you looking now? I don't see it here anymore. I have to turn around now. Okay. I want to make sure I'm looking at the same place for what you're saying.
Q. That's fine.
A. So what was your question?
Q. So my question is, again, the analyst gives us the approximate structure concentration in terms of structures per gram, correct?
A. Correct.

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Q. And it says 202 million, correct?
A. That's what it states.
Q. Now, so that's Chinese talc.
I need to offer these.
MR. PANATIER: Your Honor, we offer 3695-252, 253 and 247.
MR. DUBIN: Objection based on what we've discussed.
THE COURT: Thank you.
Objection is overruled. These are now in evidence.
(Plaintiff's Exhibit 3695-252 was moved into evidence.)
(Plaintiff's Exhibit 3695-253 was moved into evidence.)
(Plaintiff's Exhibit 3695-247 was moved into evidence.)
BY MR. PANATIER:
Q. Sir, I'd like to show you another document. This one is Rio Tinto, but that's the same company, correct, or the same entity that was supplying talc to Johnson & Johnson, right? Is that right? Sorry, sir? Is that correct?
A. I'm sorry. I was reading it. What was your question?

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Q. Rio Tinto, again, that's what later became Imerys?
A. That's correct.
Q. Okay. And you've seen this document before; correct, sir?
A. Yes, I have.
Q. Now, this is --
MR. DUBIN: May we approach about this document?
THE COURT: Sure.
(Sidebar.)
MR. DUBIN: Johnson & Johnson (inaudible) being asked about fibrous material identify (inaudible) Dr. Sanchez was asked about this these pictures (inaudible) what he reviewed actual product, and we're really getting hamstrung here having things --
THE COURT: You already discontinued use at Argonaut.
MR. HYNES: (Inaudible).
THE COURT: The purpose for which you're seeking to use this document?
MR. PANATIER: It goes to the fact that he said that based on what's in Argonaut there's -- nothing shows, they went through all

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yesterday. And this goes to show that had they, it doesn't matter what the timing is, had they looked in the Argonaut and had this analysis done, this would have been the result on any date. That's the point. It's there. It's a mine. It's millions and millions of years old.
MR. DUBIN: Your Honor, if the question is had we looked at bottles from around that time period or from the Argonaut mine and done analysis on it would we have found this. This expert knows from looking at the bottles themselves what we would have found.
THE COURT: That was relevant in the compensatory phase and a jury determined that there was asbestos in the product during the relevant time frame and that it caused the mesothelioma of these plaintiffs, so that issue is not in dispute. The issue now is the conduct of Johnson & Johnson. So what did Johnson & Johnson know or should have known and what kind of testing they did. And you established all of that on direct yesterday, the kind of testing, what was known about the mines, selective mining, all of that.
So on cross-examination as to what's known or what should have been known, this is

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permissible cross-examination. To have him go through his testing of the product, that was already resolved by the prior jury. It's not the issue for this jury.

MR. DUBIN: I want to put one thing on the record.

THE COURT: Sure.

MR. DUBIN: Your Honor, we disagree that the jury's finding precludes us from responding to something like this with this testing. Although a jury may have found that at some point during the period of exposure for these plaintiffs there was some asbestos exposure, that does not mean that they found at every point that there was asbestos exposure or that they found material similar to this in Johnson & Johnson's product. And we are being precluded, we're now making an assumption that the jury found at all times there was asbestos and that there was this kind of material in the products made from Argonaut in Johnson & Johnson, and we are -- we would like to be able to respond to that with evidence that Dr. Sanchez has tested products made from ore sources from Argonaut and has not found these kind of materials in them. And I have made my statement.

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THE COURT: Thank you.

Whether or not asbestos was found in every single bottle is not the issue, and because a jury determined below that there was asbestos in the product in sufficient quantities that it became a substantial factor in the development of the mesotheliomas. If we have testing or testimony by Dr. Sanchez as to, well, these bottles or none of the bottles I tested was it in there, then we get into a second trial, a retrial of what happened below, and let's bring Dr. Longo back and do that, and that's not the issue in front of this jury.

So your exception is noted. This is permissible cross-examination. You may continue.

(Sidebar ends.)

BY MR. PANATIER:

Q. All right. Did I give you a copy?

A. Yes, I have a copy.

Q. So this is from Julie Pier at Rio Tinto/Imerys, the supplier.

Now, in fairness, this report is five years after Johnson & Johnson stopped using this deposit, correct?

A. Yes. This is from 2008.

Q. Okay. But what is in a deposit is

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millions and millions of years old, right?

A. I'm sorry?

Q. What is in a deposit is millions and millions of years old, billions?

A. It can vary, but it would depend.

Q. The earth is about 3.8 billion years old, right?

A. I think it's older than that.

Q. Okay. All right. That's fair. It's old?

A. It is old, yes. That's correct.

Q. These deposits are old?

A. We're talking about Vermont here?

Q. Yes.

A. They are old deposits, but not as old as the earth.

Q. Okay. All right.

Now, you see there's a sample, it says, "Request." 3685-248. This is a sample of acicular mineral material collected at the Argonaut mine which was submitted for identification. And the result was, "The sample was identified as asbestiform actinolite amphibole." Correct?

A. That's correct.

Q. That's asbestos?

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A. Yes. This is clearly asbestos here.

Q. These are SEM images, which are scanning electron microscopy, correct?

A. That's correct.

Q. That first one, I don't know, can you see the magnification on that one?

A. This is a bulk sample, but it's 100 times.

Q. That's 100. And then what's the bottom picture?

A. Appears to be -- it's a thousand times.

Q. All right. So they're not looking at it at 20,000 times or anything like that. We're getting a picture, a visual, of kind of what this material looks like in its bulk state, correct?

A. That's correct.

Q. Now, let's chat about the test method a little bit. You know what, one last thing on Italian talc. This is the Paoletti paper that you and Mr. Dubin talked about yesterday.

Do you recall that?

A. I do.

THE COURT: What's the marking on it for identification?

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MR. PANATIER: For identification, this would be S-6.
THE COURT: Thank you.
MR. DUBIN: In evidence?
MR. PANATIER: I'm not going to offer.
(S-6 was marked for identification.)
BY MR. PANATIER:
Q. All right. This is the paper that you had discussed yesterday. "Evaluation by electron microscopy from 1984, techniques of asbestos contamination in industrial, cosmetic and pharmaceutical talcs."
And one of the questions Mr. Dubin asked you was, well, does this say anything about Johnson's Baby Powder, and it doesn't say anything about Johnson's Baby Powder directly?
A. That's correct.
Q. Okay. Typically in academic papers, if a product is being studied, they typically don't name the product?
A. I would think that would be accurate. Yes.
Q. It can happen, but it doesn't happen often; fair?

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A. Not normally, yes.
Q. Here, under introduction, it says, "The most common minerals that may be found mixed with talc in mineral deposits are listed in Table 1. Among them, two fibrous kinds of amphibole, tremolite and anthophyllite, and a fibrous kind of serpentine mineral, chrysotile, constitute some of the best known varieties of asbestos."
And I think you had told me earlier that serpentine is the general category for chrysotile, correct?
A. Serpentine is a mineral group name. It's like an amphibole. You would then go from the group into the individual species. So chrysotile is part of the serpentine group. There's a bunch of other ones as well.
Q. Right.
So serpentine would be the category that chrysotile would be in?
A. It's a mineral group. Yes.
Q. Okay. If we go to results, page 227, they say, "29 different samples" --
A. I'm sorry. 227, you said?
Q. 227 on the top. There you go.
A. Okay.

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Q. "29 different samples of talc for industrial, cosmetic and pharmaceutical uses have been analyzed; 15 from the Italian market and 14 provided by the European pharmacopeia from the International market and from various geographic areas."
So we're just going to focus on Italian here. Okay?
A. Okay.
Q. And, of course, Johnson & Johnson was using Italian talc for use in the United States through the late '60s and then again in the early '80s because of the mine strike.
Do you recall that?
A. That's my recollection.
Q. "To evaluate the pollution due to asbestos in the studied talcs, the fibrous kinds of amphiboles, tremolite and anthophyllite and the fibrous kind of serpentine, chrysotile, have been investigated." And then they refer us to a table.
"As reported in Table 7 through 9, in eight out of the 15 Italian talcs the presence of asbestos fibers has been revealed, in seven samples there were fibers of tremolite and in one sample there were fibers of chrysotile."

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Right? That's what it says?
A. You read that correctly.
Q. And we could go to the tables. I want to look at cosmetic and pharmaceutical. And they said Table 7 through 9. So 7 is industrial talc, they found some there. Then we go to pharmaceutical. This is the Italian, correct?
A. These are samples out of the Italian market, correct.
Q. Correct.
They found four out of five that contained tremolite asbestos?
A. They are reporting tremolite fibers, yes.
Q. Under what is the heading there?
A. Asbestos fibers, yes. I'm not disagreeing with you.
Q. And for cosmetic talc, they found two out of six to contain tremolite asbestos, correct?
A. That's correct.
Q. They even provide us some nice pictures, right? There's a tremolite fiber, correct, on Figure 4?
A. That's correct. That's what they identify it as.

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Q. And Figure 5, you can see the chrysotile fibers, right?
A. It appears so. Yes.
Q. Okay. Now, you're aware, sir, that Johnson & Johnson was concerned about this article, correct?
A. I'm not aware of that.
Q. This is Exhibit 3695-250. And the reason I want to show this to you is because you had said well, we don't know whether it has anything to do with Johnson's Baby Powder. That's why I'm showing it to you.
Do you see this is a memo from September 26, 1984, Johnson & Johnson?
A. Yeah. Let me please read it first.
Q. Sure. And this is in evidence already. Go ahead and read it. Let me know when you're ready.
A. Okay.
Q. And you see that Bill Ashton, William Ashton states, "Attached is a copy," and he's sending this to Talc de Luzenac; that's what later became Imerys, right?
A. Yes. Imerys was -- I'm sorry, what was that question? I'm not following.

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Q. Luzenac is the entity that later became Imerys?
A. Yes. Imerys Talc bought some of the talc deposits from Luzenac.
Q. "Attached is a copy of a paper which is very important to the talc industry in your territory. It alleges that a substantial number of talcs contain fibers and/or asbestos. It is published by a reputable organization in Rome. It has just appeared in this month's issue of Regulatory Toxicology and Pharmacology here in the states."
And it references the article you and I just looked at, right?
A. It appears to.
Q. So Mr. Ashton, from Johnson & Johnson, says this paper comes from a reputable organization, right, or published by a reputable organization, correct?
A. That's correct.
Q. This is already in evidence. This is 3695-251. You see that? That is a memo, October 23rd, '84?
A. I see that.
Q. That's a little less than a month after the letter to Talc de Luzenac?
A. Time-wise, yes.
Q. Do you see that it's signed by the same individual, Mr. Ashton?
A. I see that.
Q. If you turn to the second page, please, sir, under talc --
A. Can I have a chance to skim through this? Sorry.
Q. Of course. Sure. Sure.
A. Okay. I read it.
Q. Do you see where Mr. Ashton references the Paoletti article again?
A. I see that.
Q. And he says, "I spoke to some of the ASTM and ISO officials about the uncomfortable business aspects of the recent Paoletti article hoping they might have some ideas on how to compromise it."
Is that what he said?
A. He did say that.
Q. So what we know is that Paoletti put out an article that addressed Italian talcs; true?
A. Markets bought off of the Italian market, yes.

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Q. And that Mr. Ashton was aware of this at Johnson & Johnson, correct?
A. It appears so.
Q. He said that it was published by a reputable organization?
A. He did.
Q. And a couple weeks later, he said we need to figure out ways to compromise it, correct?
A. He was talking to these other committee groups looking into it, whether it's reasonable. But yes, that's the language he used.
Q. Compromising?
A. That's the language that was used.
Q. Let's chat, I think this is the last issue and then you and I will be finished. Let's chat about Johnson & Johnson testing method 7024. This is Defense 8393.
So this is the test method that Johnson & Johnson uses for transmission electron microscopy, correct?
A. This is their internal method, yes.
Q. Okay. And the title is, Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy. So what they're trying to find is asbestos, correct?

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A. Asbestiform minerals, yes.
Q. Asbestiform minerals is a long way of saying asbestos, right?
A. Not entirely, but it can be used that way.
Q. Are they looking for asbestos or are they not?
A. They are, but there's other minerals that can be asbestiform that aren't asbestos, so there's just a nuance there.
I'm not trying to disagree with you. I'm just trying to be precise.
Q. Okay. If we go to the page marked 3 of 6 or 5 of 9, however you like it.
A. I'm there.
Q. All right. A few things it says here. First of all, I want to go to 9.0, "Preparation time per sample, including preparation of related materials, is one hour. Analysis search time per sample is a maximum of two hours." Right?
A. I see that.
Q. So there's a top amount of time that the analyst can actually spend on this if you're following the method?
A. I don't interpret it that way. This

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is talking about routine, routine sampling and analysis. This is what you'd expect, about an hour to do it and no more than two hours to analyze it.
Q. Okay. Under definition of a fiber, it says, "An elongated particle with parallel sides and an aspect ratio," that's length to width, "3-to-1." Greater than or equal to 3-to-1, right?
A. Correct.
Q. "The definition employed may vary with the needs of the client."
And then it says you scan your grid squares, et cetera, each asbestiform mineral is recorded as to type, chrysotile, tremolite, anthophyllite, et cetera, structure, whether it's a bundle, a clump, a fiber and dimensions, length and width. Right?
A. That's correct.
Q. It also has something that you have brought up once or twice called the limit of quantifiable detection, right?
A. That's correct.
Q. And what this says here --
A. Which page are you on now?
Q. 2 of 6. 4 of 9.
A. 4 of 9. Thank you.

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Q. Yep.
What this says here is "The detection of five or more asbestiform minerals of one variety in an analysis constitutes a quantifiable level of detection. When no asbestiform minerals are detected, a representative fiber size is used to calculate a detection limit."
Okay. So, what that means is, is that in order to say that asbestos is present, you have to have five or more fibers of any one type, correct?
A. In order to quantify how much is present, yes.
Q. Right.
To say that, to report it as asbestos present, quantifiable, correct?
A. Correct. This is defining what the statistical basis, what would be a level that you could actually put a number on.
Q. Because we've seen this. The jury has seen this. Below quantifiable limit of detection in a number of reports, right? That would mean, in this context, that if you saw -- I'll change colors so I don't get too confusing here.
So if you saw four chrysotile fibers

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in this tiny, tiny, tiny bit of talc, you would report it, you could report it as below quantifiable limit of detection, correct?
A. If the statistics you're using is a five, what they're doing here, then yes.
Q. And so I'm just asking you under the method, that is how you could report it, correct?
A. Yes.
Q. If you had four anthophyllite fibers, and this is all we're saying asbestos, we're not saying anything else, if you had four anthophyllite asbestos fibers, you could report below quantifiable limit of detection, correct?
A. According to the statistics, yes, that would be a statistically valid way of reporting results.
Q. If you had four tremolite fibers, you could report below quantifiable limit of detection, correct?
A. Same answer. Yes.
Q. And lastly, if you had four actinolite fibers, same answer, correct?
A. That's correct.
Q. So in practical terms, let's say you've got your grid, right, and you're looking

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down, you're looking in the -- you actually don't look down in the TEM, you just look at a screen, right?
A. You do look at a screen, but you are leaning forward.
Q. Okay, leaning forward.
A. It is projected below you, so...
Q. Not in the eye pieces?
A. At times you are, yes.
Q. All right. Well --
A. Again, I'm not trying to quibble.
Q. That's fine. That's fine. Let's just talk about how this method works.
So you're looking in the view, and typically you're looking at ten grid openings, correct?
A. I think if you follow this method, yes, I think we're doing ten grid openings over two grid preparations.
Q. We talked about that yesterday; five grid openings on two different hundred-space grids?
A. Correct.
Q. Let's say you're looking down and your entire area that you looked at summarized in this square, okay, and you have four, you see

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objectively, you see four fibers of chrysotile asbestos, correct?
A. It's all hypothetical. Okay.
Q. Yeah. Under Johnson & Johnson's method, you're allowed to report that as below quantifiable limit of detection, correct?
A. It would be below your ability to quantify, yes.
Q. Let's say you also see four fibers of tremolite. Same answer, correct?
A. That's correct.
Q. And you also see four fibers of actinolite. Same answer, correct?
A. That's correct.
Q. And you also see -- where's my green? -- four fibers of anthophyllite, correct?
A. Again, hypothetical, yes.
Q. Well, in fact, sir, I've shown you this before, this is 3695-249.
Sir, you've seen that document before, correct?
A. I have.
Q. And that is from Julie Pier, and she worked at Imerys, right?
MR. DUBIN: Same objection as before,

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your Honor.
THE COURT: Thank you. Objection noted. Overruled.
Continue.
A. What was your question? I'm sorry.
Q. It's from Julie Pier?
A. Yes, it is.
Q. To Tim Hicks. And she's explaining the detection limit on Johnson & Johnson's method, correct?
A. That's correct.
Q. And she says -- thanks.
She says, "Recently you asked for an explanation of the reported detection limit of method TM 7024 analysis of powdered talc for asbestiform minerals by TEM performed on Grade 66."
That's the baby powder, right?
A. Correct.
Q. "The method states that the limit of quantifiable detection is five fibers. In other words, if only three fibers are detected, we could say that the amount detected is below the quantifiable detection limit." Right?
A. Following the method, correct.
Q. So under this method, the technician,

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the analyst, can objectively see asbestos present in the sample of baby powder and they are permitted, under the method, to then put in the report below the quantifiable limit of detection, correct?
A. Based on the statistical uncertainty chosen, yes.
Q. Lastly -- yeah.
So I'll offer that one I just used, your Honor. 3695-249.
MR. DUBIN: Same objection, your Honor.
THE COURT: Thank you. Noted. Overruled. Now admitted into evidence.
(Plaintiff's Exhibit 3695-249 was moved into evidence.)
BY MR. PANATIER:
Q. And Moshe pointed out to me, he asked me to go back to this, paragraph 8, background correction. 'Cause I think you brought this up yesterday that, I think you said, you know, early on --
A. I'm sorry. Which page are you on?
Q. Sure. This is 3 of 6, 5 of 9.
You said there was a time where people expected more asbestos as a potential

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contaminant, correct?
A. In the past it was much more a problem from an environmental perspective, yes.
Q. Okay.
A. But you still have to determine your background levels within your laboratory and also within the analysis you're performing.
Q. Yeah.
What this says here is that, under background correction, "As of the time of this writing" -- and this is 1995 -- "background correction has not been necessary. The amount of background asbestos detected has been insignificant in comparison to the levels of asbestos found in contaminated samples."
You're aware that's in there, correct?
A. I am.
Q. Okay. I want to take you back to the start of our conversation yesterday. And we have talked about the sensitivity of different methods, right?
A. Correct. To some degree, but yes.
Q. We've talked about how TEM as a tool can be more sensitive than light microscopy,

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correct?
A. I think it's incorrectly to characterize it that way. It is better at looking at the -- it is able, it's sensitive from a particle size, it's more sensitive for a particle size aspect, yes.
To know what those finest particle sizes are you have to use TEM. There's no other way to look at those. But as an overall sensitivity comparison you can do PLM analyses that would give you a much finer sensitivity than a TEM.
But again, it's based upon what the analysis is and the scope of what it can and cannot do every time.
Q. Let me ask a more simple question.
TEM can see some things that the light microscope can't?
A. And vice versa, yes. That's true.
Q. Right.
Like you said, if we've got this big fat fiber or bundle of fibers under PLM and I'm looking through this microscope, right, well, I could see that there?
A. Yes.
Q. But with TEM, we would be taking a

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very, very small electron beam and it might go right past that big guy?
A. It wouldn't be that way. The issue is the larger particles, you can't even look at them. I mean, your magnifications are -- you would never -- you don't use TEM to look at the big particles. You use TEM only to look at the fines.
Q. You would be looking at a teeny little dot --
A. Yes.
Q. All right. So we talked about how, in each test, there's about .00002 grams that are actually evaluated. Can you tell me, in terms of actual weight, how many grams are actually analyzed in the ten grid openings that are looked at? Is it a millionth of a gram?
A. I've never done the calculation.
Q. It's less than this, right?
A. Yes. It would be less than that.
Q. Substantially less than that?
A. It would be less than that.
THE COURT: For the record, you're pointing at less than --
BY MR. PANATIER:
Q. Less than .00002 grams. Right?

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A. That's correct. It would be, it's less than that.
Q. But let's say it was this. Let's say it was this amount that was being analyzed with every test.
Now, I've asked you this before. Johnson & Johnson, generally speaking, starting in the mid '70s or so, was doing quarterly tests with TEM, correct?
A. Quarterly composite testing, yes.
Q. Right.
And what that meant was, first of all, they would take, they would do J4-1 on every two silos, correct?
A. I'd have to review the documents for the specific testing frequencies at that specificity.
Q. Well, do you know how big their silos were?
A. Not as I sit here today.
Q. Okay. That's fine.
They would do quarterly composite testing, which would mean that they would take, they would take kind of a mixture of things they had pulled over the quarter and they would test it one

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time?
A. That's correct. The material that was being processed, they were taking, they were taking samples and then compositing those samples into a quarterly composite over that period.
Q. Right.
And they would do one TEM testing each quarter, right?
A. I believe that's accurate.
Q. And then a later time came where they went to doing biweekly TEM test, every two weeks, right?
A. No, I think they changed the frequency of their compositing to, from -- to a biweekly composite.
Q. Okay. Let me just cut to the chase.
A. Thank you.
Q. You've reviewed a lot of documents; Imerys documents, Johnson & Johnson documents. And you and I have been through this before.
Overall, there are about, the last time you and I talked about it, 365, but let's say about 400 total TEM tests on Johnson & Johnson's talc.
A. Okay.

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Q. Would you agree with that?
A. Somewhere in that ballpark.
Q. Okay. It's in the ballpark of 400 tests. So 400. And I'm going to put a little baseball diamond there 'cause that's in the ballpark.
Okay. Now, if we want to know how much talc then has been evaluated, we could -- we know the way less than this per test, the .00002, but if we just took this and we wanted to ballpark how much total asbestos -- total talc that Johnson & Johnson has actually evaluated by TEM in terms of weight, you just take that times that?
A. Well, you're going extrapolation, but you could do it that way.
Q. I'm not talking about extrapolating. I'm talking about the actual amount analyzed.
A. Sure.
Q. Okay. And we could do that. I still have my calculator. We just multiply, right?
A. I believe that's accurate. Yes, I believe that's correct.
Q. So it would be, if it's 400 tests, 400 times .00002 equals .008, right?
A. Grams, yes.

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Q. I'm going to put approx, approximate, total talc tested. I'm going to put J&J talc, J&J talc, by TEM is about .008 grams, right? That's what our math was, right?
A. In your hypothetical, yes.
Q. Well, in my hypothetical I've overestimated the amount that was actually studied for each TEM test, haven't I?
A. Well, you're ignoring a few things, but yes. Using the numbers that we just discussed, that is the correct number.
Q. Right.
Now, when we talk about sensitivity of different tests, I've asked you before, in really kind of simple terms, we could say if you have a bathroom scale, that's less sensitive than a scientific scale, right?
A. Not -- again, depending on what you need to weigh, you use different scales. That's the way to look at it.
Q. Right.
A. So if you're trying to weigh your weight of a person to a certain precision, you would then choose a scale that would be appropriate to measure that person to the precision you wish to

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measure them.
Q. Not a bathroom scale.
A. That does not appear to be a bathroom scale.
Q. This would be a scientific scale, right?
A. It is a scale. Yes.
Q. Okay. Maybe you have a better one. It's the Gemini 20. Is that any good, do you know?
A. I don't know anything about your scale. But again, when we use scales, we always calibrate them to know if they work or not.
So even with a scientific scale, you still have to go through calibration of the unit.
Q. Okay. So this one is showing zero and it's got this little guy. Do you know what this is for?
A. I assume it's to check the weight.
Q. And it says 10G. Does that mean ten grams?
A. That's correct.
Q. So if you put this on here, it should give us close to ten grams. Oops. Sorry.
10.01415. So it's very, very close, correct? Can you see that?

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A. I see that.
Q. Sorry. This thing kind of --
A. You shaded it at one point. I think it helped.
Q. Oh, light. Okay. That helps. Okay. We see that it's -- there. If I shadow it, we're very close to 10 grams. Okay?
A. Don't move.
Q. Okay. So we're going to take that off. And actually I think it's got this feature called tare or tare, and if we press that I think that zeros us out. Okay. Never mind. Okay. We're back to zero. Okay. So here's where I'm going. Total amount of talc tested by TEM by Johnson & Johnson. If we want to know if that's less than the weight of one of these Ice Breaker breath mints, we can just weigh it, right?
A. That's true.
Q. So an Ice Breakers brand breath mint weighs about 8/10ths or thereabout of a gram, would you say?
A. That one does, yes.
Q. This one does. And so a mint weighs .8 grams and we have these convenient 8s here. How much heavier is

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that mint than the total amount of talc that Johnson & Johnson, by our discussions, has tested by TEM?
A. It would be 100 times more.
Q. 100 times.
A. Two orders of magnitude.
Q. So if we wanted to visualize for our jury that amount, we would have to take this mint and we would to divide it by a hundred times, correct?
A. No. The density of the mint and the density of the talc are different, so you wouldn't be -- the volumes wouldn't be the same.
Q. I'm not talking about cutting it into tiny pieces. We would take 1/100th of this mint?
A. To do what?
Q. In terms of weight.
A. For weight perspective, yeah.
Q. We would take 1/100th of the mint to get .008 grams, right?
A. Yes.
MR. PANATIER: Those are all the questions I have.
THE COURT: Thank you. Redirect?
MR. DUBIN: Yes, thank you.

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I doubt I'll finish before lunch, so what time would your Honor like me to go until?
THE COURT: No later than one o'clock.
MR. DUBIN: It won't matter to me to stop, so I'll just pick whenever. I'll see when people look hungry.
REDIRECT EXAMINATION BY MR. DUBIN:
Q. All right. Hi, Dr. Sanchez. How are you?
A. I'm well.
Q. So I want to start with one of the questions that you were asked early on about these boards. Okay? And the question you were asked is whether the boards are accurate, right? You recall that?
A. From Mr. Panatier?
Q. Right.
A. Yes. I recall.
Q. And in that sense, if we look in these documents can we find these words there, right?
A. Yes, we can.
Q. But if we want to talk about these boards as a whole, if someone were to suggest that

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these boards represent actually scientific valid findings of asbestos in Johnson & Johnson's products, would that be accurate?
A. No, it would not be.
Q. Okay. And we talked a lot about this yesterday, but I want to go through some of the documents that you were shown and discuss them. One thing that you were asked about fairly early on was Dr. Pooley's report. And what the plaintiffs showed you, I'm truly awful about this, is a section of a very long report that he wrote regarding, a section of a very long report that he wrote about his mine visit in Italy. And just even looking at the document itself, they read to you this part. It says, "Particles formed from the amphibole mineral found at the mine were hardly fibrous in character, the majority of the tremolite breaking to give compact particles. Those fibers formed were short and had a very large diameter when compared with the commercial varieties of asbestos." You see that?
A. I do.
Q. And I'm going to come back to that, but first I'd just like to point out what

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plaintiffs' counsel did not read in the next sentence from this document.
What does it say?
A. You want me to read it?
Q. Yeah.
A. "No amphibole or chrysotile mineral was detected in any of the numerous powders examined."
Q. So here he's talking about the mine site, right?
A. Yes.
Q. Is there any question about whether Dr. Pooley, in the very document they asked you about, whether he said -- what did he say about whether there was asbestos in any of the Johnson & Johnson powders?
A. Well, the powders he tested here, he says they were not detecting any asbestiform minerals in those powders.
Q. Was there any asbestos in any of the Johnson & Johnson product that he evaluated?
A. Not to my recollection.
THE COURT: Counsel, for the record, you're going to need to identify that.
MR. DUBIN: Sorry. This was the

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document that they had used. It was part of Defense 8372.
THE COURT: Thank you.
MR. DUBIN: No problem.
BY MR. DUBIN:
Q. And let's just assume for a second that we're going back again to see whether it was true or not. Let's assume, let's go with the plaintiffs' idea that somehow this document says there's asbestos in Johnson & Johnson. Okay? Forget what we just talked about for one minute. Okay?
A. Okay.
Q. We went through this yesterday, and this is a slide made from admitted exhibit, Defense 8372.
Who did Johnson & Johnson give that very same Pooley report to that we were just looking at?
A. This was part of their submission to the FDA at this time.
Q. So this very document that they cross-examined you about and said that it found asbestos, who did Johnson & Johnson give it to?
A. The FDA.

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Q. And in terms of whether Dr. Pooley actually did think there was asbestos in those samples, there was a cover letter for that report, right?
A. There was.
Q. And we looked at that cover letter yesterday, Dr. Pooley writing to Dr. Shelley at Johnson & Johnson. And what did he conclude about -- what did he tell Johnson & Johnson about whether there was asbestos in that Italian mine they were using?
A. He says, "No chrysotile was found at the mine or in the samples taken. Some tremolite was located, but was not asbestiform in character and has not been detected in the 00000 talc imported into Great Britain for the past year, nor in shipments dating back to 1949. I hope that it is of some interest to you."
Q. And despite Dr. Pooley saying that, is that entry on plaintiffs' board of J&J's internal documentation in this case having to do with asbestos?
A. No.
Q. Is it listed on their board?
A. It is on their board.

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Q. Is that a finding of asbestos?
A. It is not.
Q. And then you were asked a little bit about Dr. Pooley's testimony, and again, that's not something you've reviewed.
Just to put it in context a little bit, this was the deposition that he was talking about, just to show you some additional parts of it, talking about looking at the batches of talc and old samples, "What did you conclude after looking at those shipments and all the various samples? No fibrous asbestos minerals detected."
So that's something that you weren't shown from Dr. Pooley's deposition?
Do you see that?
A. I do.
Q. Okay. And he was also asked, "And do you believe that all the testing that indicated there's no asbestos in Johnson & Johnson's talc are conclusions that, as you're sitting here today looking at all this material, do you stand by the work that you did?"
And what was his answer?
A. "Yes."
Q. Again, so is it important in some of

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these contexts to look at some additional information?
A. It's always good to have more information.
Q. And when I say whether all of these findings were, represent scientifically valid, you know, one of the other ones I thought was very interesting we didn't go back to with -- plaintiffs' counsel didn't go back to is this Dutch Consumer Organization. I want to talk about that. 12/13/73.
MR. PANATIER: Your Honor, that's beyond the scope.
THE COURT: Sidebar.
(Sidebar.)
THE COURT: It does seem to exceed the scope of cross-examination.
What's the purpose?
MR. DUBIN: Yes. He asked the witness, your Honor, are these boards accurate, right. And so he put into play the accuracy of the boards. And now I'm trying to explain the witness's answer when he said it was accurate, what it meant and what it didn't mean, these board entries. He asked about the boards in their entirety and then I'm going into that very same issue.

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THE COURT: Thank you.
Yes?
MR. PANATIER: I asked him if the boards, if what is reported on the boards is in the documents and he said yes. Now he's trying to get into the substance of the board. I didn't talk about the Dutch Consumer Organization.
THE COURT: He's using it by way of an example.
How many of these ways of example are you doing?
MR. DUBIN: Most of them focus on specific documents that he did instead of other ones. I don't think I have --
THE COURT: Okay, fine.
(Sidebar ends.)
BY MR. DUBIN:
Q. So again, the reason I'm asking this is 'cause he asked you whether the boards were accurate, so I'm just trying to put in context your response. Otherwise, I'll talk more about specific documents he raised.
Just as an example, you were asked were the boards accurate. And is it accurate that there's a document from the Dutch Consumer

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Organization, 12/13/73, that says the word asbestos?
A. Yes.
Q. Does that mean that the Dutch Consumer Organization, in fact, found asbestos in Johnson & Johnson's product?
A. No. It does not.
Q. And we looked at an issue like this. This is one of the examples we looked at yesterday.
Can you remind the jury what the problem was with what the Dutch Consumer Organization did?
A. Yes. Their definition of asbestos would include talc. Any mineral that would have magnesium and silicate in it like talc, if it had an elongated or needle form would be called asbestos under that method.
Q. And so is it any surprise that the Dutch Consumer Organization could find talc in talcum powder?
A. No. Again, you would -- in any talcum powder sample you will find some fibrous talc. You will see talc that are elongated, that have a fiber shape. In any talc you look at you will find those.
Q. Is it an accurate characterization to

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somehow say that that's a finding -- internal documentation by J&J of a finding of asbestos in this product?
A. No. That would be incorrect.
THE COURT: Counsel, for the record, what was that?
MR. DUBIN: I'm sorry. The document that I'm displaying right now is Defense 7070 admitted.
THE COURT: 77 what?
MR. DUBIN: I'm sorry, 7070 admitted.
THE COURT: Thank you.
BY MR. DUBIN:
Q. So let me focus on some of the documents you were specifically asked about then, because I don't want to repeat myself.
So one of the documents you were asked about also, and we'll talk a little bit more about the whole Lewin thing, but you were asked about this analysis of Italian medicated Grantham talc from Rolle's files that includes also discussion of Lewin Shower to Shower.
You see here where it says that there's a finding of rod or needle tremolite? Does that mean that's asbestos?

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A. Not necessarily. No.
Q. And we know that also if we look at what the FDA found --
THE COURT: Counsel, I don't want to interrupt you, but --
MR. DUBIN: I am just assuming the plaintiffs --
THE COURT: No. You're creating a record. The record can't see what was said.
MR. DUBIN: I understand. It's 3441, Plaintiffs' Exhibit.
THE COURT: Thank you.
BY MR. DUBIN:
Q. And then if we look at what we looked at yesterday, this D-8869, this whole idea about tremolite and tremolite being found in the 1970s, what does this show about whether the FDA was aware of tremolite, that tremolite could be in talc dating all the way back into the 1970s?
MR. PANATIER: Your Honor, I object to this on outside the scope and I have more actually, I mean, sidebar.
THE COURT: Sure.
MR. PANATIER: Sorry.
THE COURT: Can you take that down,

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please?
(Sidebar.)
MR. PANATIER: So it's scope. I asked him about Sample 84. The FDA, in the '70s, found asbestos in Sample 84, 107,000 fibers per gram, and he said yes and I moved on. This now he's putting up some other samples of 196 which he did yesterday. It's outside the scope. Again, it's not part of this.
THE COURT: Sorry. I thought I was going to sneeze.
MR. PANATIER: Bless you.
MR. DUBIN: Your Honor, we're trying to put the documents that he used with the witness in cross in context that this idea of somehow Johnson & Johnson is finding tremolite, some hidden (inaudible) with the FDA. I'm simply putting his document into context quickly.
You know, his idea of scope is incredibly tight at this point as if I can only ask about the precise document that he puts on the screen whether there's a topic.
THE COURT: That's generally what scope means. I'm not going to allow it. If you have a question about that precise document, but

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otherwise, that confuses the jury.
Listen, I let you do the one as an example, but if you're going to use that, you're going to have to tell the jurors that this was not the document that was referenced or not the test that was referenced by counsel. That's fair.
MR. DUBIN: I understand that.
THE COURT: You have a choice.
MR. DUBIN: Okay. I'm fine to identify, that's fine.
THE COURT: Right. But then not exceeding the scope means not exceeding the scope.
MR. DUBIN: I understand.
THE COURT: That's what it means in this jurisdiction.
MR. DUBIN: I understand, your Honor. As I articulated, I am trying to stay within the scope. I will be mindful of your Honor's admonishments.
THE COURT: You're going to stay within the scope.
MR. PANATIER: I didn't even use the document, by the way. I just asked him a question.
THE COURT: He's allowed to use the document if it was a document that you referenced.

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MR. PANATIER: Sure. And that's not.
THE COURT: That would be within the scope. Stay within the scope.
(Sidebar ends.)
BY MR. DUBIN:
Q. We just showed a document about the internal discussion of tremolite at Johnson & Johnson.
Have we also discussed documents, and plaintiffs' counsel discussed them with you, showing that the FDA was aware, in the 1970s, that there could be tremolite in cosmetic talcs?
A. Yes.
Q. And so I want to talk a little then about the documents that you went through with Dr. -- about Dr. Lewin, and this was one of the first ones that the plaintiff showed you. It's Plaintiffs' Trial Exhibit 2852, or it would be if we could see it.
And so we all understand where we are, sometime in the early 1972, Dr. Lewin claimed to find asbestos in a number of different products, primarily by using a technique called XRD, right?
A. Yes.
Q. And then again, to provide some

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context to that, we talked about the fact that, and this we discussed yesterday, just to provide a little historical context, Defense 7073, what happened after Dr. Lewin made those initial claims?
A. Again, there was a lot of research that was done about what was found and whether that was accurate or not.
Q. And we also, again, for context, went through this, Defense 9262. And what ultimately was the conclusion about whether those initial allegations by Dr. Lewin were correct or not?
A. Again, this is Walter C. McCrone speaking here. He calls that the original report was grossly wrong.
Q. Okay. And you were asked specifically about some of the testing that was done, you know, he put up on the board the specific ones that were done by XRD, right?
A. Correct.
Q. And can you remind the jury why Johnson & Johnson was having certain experts look at Dr. Lewin's findings by using the technique XRD?
A. Yes. At that time, Lewin was using powder X-ray diffraction and claiming to find asbestos. So Johnson & Johnson went to experts in

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the field of powder X-ray diffraction to have them evaluate those results and test samples by that same methodology to see what they were seeing.
Q. And again, these were written up on the board by plaintiffs' counsel, so let's again look at what people actually concluded.
We looked at Defense 8372 with this expert from M.I.T., and what was he saying about Dr. Lewin's findings?
A. He says, "My conclusion is that no tenable evidence has been advanced to show that any Johnson & Johnson product was made with talc which contains chrysotile asbestos, and no tenable evidence has been advanced to show that the product as sold and manufactured contains chrysotile asbestos."
Q. And we looked at this conclusion from Dr. Gordon that they asked you about on cross-examination. This was Defense 8372. And did he conclude whether there was asbestos or not?
A. Based on the X-ray diffraction testing, he says no evidence for chrysotile or tremolite was found.
Q. We looked at the Colorado School of Mines, Defense 8372, and what did they conclude

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about whether Dr. Lewin was right?
A. It says, "The above data does" -- this is speaking, again, to x-ray diffraction data. "The above data does not indicate the presence of chrysotile."
Q. We looked at experts from Carnegie Mellon. That was Defense 8372 --
MR. PANATIER: Your Honor, scope and leading, your Honor.
THE COURT: Scope is fine. Just don't lead.
MR. DUBIN: I'm just asking did -- okay.
BY MR. DUBIN:
Q. Did we look at this document yesterday?
A. We did.
Q. 8372?
A. Sorry. We did.
Q. And I don't think what did they find is leading; what did they find?
A. Again, looking at the X-ray diffraction information, he agrees there is no positive evidence for the presence of chrysotile in the Shower to Shower product.

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Q. And so we've now talked about some XRD analysis, and I want to talk about the other document that plaintiffs asked you about, about this.
THE COURT: For the record.
BY MR. DUBIN:
Q. This was a document, Plaintiffs' Trial Exhibit 2424, and it was a summary of a FDA meeting back in, I think that's August 11, 1972 -- 1972, and one of the things they focused on with you is this.
So again, the plaintiffs' counsel asked you about what was being done to verify whether or not Dr. Lewin's results were correct.
Do you recall that discussion?
A. I do.
Q. And two parts of this document were highlighted. I want to focus on the first with you.
It says, "In subsequent discussion, Mr. Ian Stewart pointed out that light microscopy may not detect chrysotile fibers."
You see that?
A. I do.
Q. And so what's going on there?
A. The proposal of Dr. Lewin to look at

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his results to try to do some verification work was to go to the optical microscopy, to use optical microscopy. Ian Stewart of McCrone rightly points out there is a chance, using only optical, that some of the find -- fine fibers of chrysotile present, you wouldn't be able to see them.

Q. And so, if I am framing this wrong correct me, but was one of the criticisms that plaintiffs' counsel was making is that they shouldn't have been using optical microscopy to verify whether Dr. Lewin is right?

A. Say that again. I'm sorry.

Q. I think there was a suggestion that you shouldn't be using optical microscopy to verify whether Dr. Lewin was right or not because of what Dr. Stewart said.

A. No. I don't think -- optical microscopy isn't bad for this, especially at the ranges that Dr. Lewin is reporting, two or three percent. But there is always the chance if you do have some, a little bit in there and it's only in the fines, you wouldn't be able to see it by PLM.

So there's nothing wrong with what he's saying here, it's correct.

Q. Let's also just say hypothetically,

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hypothetically, if Mr. Stewart from McCrone wanted the FDA to miss asbestos if it's there, to not find it if it's there, is there any reason to tell them this?

A. You want me to assume that Mr. Ian Stewart would not want the FDA to find asbestos?

Q. Right. If that was their motive.

A. Okay.

Q. So is that something they would say?

A. I don't think somebody would say that if that was their motive.

Q. Are they telling the FDA maybe you should use a different method if you want to really find it?

A. Say that one again, I'm sorry.

Q. What are they advising the FDA you should do?

A. He's raising the concern that only using light microscopy, you could miss if there were chrysotile fibers.

Q. So what kind of microscopy would you then use if you had that concern?

A. At this point, transmission electron microscopy.

Q. So if we look then at what Johnson &

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Johnson actually did, we looked at this document yesterday --

THE COURT: Again, for the record.

MR. DUBIN: Defense 8372.

BY MR. DUBIN:

Q. In evaluating whether Dr. Lewin's findings were correct, did Johnson & Johnson do more than having its consultants look at the samples with optical microscopy?

A. Yes, they did.

Q. What else did they have them do?

A. Again, they were doing -- they had their consultants look powder X-ray diffraction, which we just talked about, they had electron microscopy conducted and in some cases, some optical microscopy was also conducted.

Q. So did Johnson & Johnson have its experts do more, less or the same amount of work to verify these allegations than the FDA was suggesting?

A. I think Lewin was suggesting it at that point, but they were doing more than what was suggested by Lewin to verify his findings.

Q. And in that respect, is that in any way comparable to what Johnson & Johnson did in its

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routine testing for cosmetic talc?

A. As I've stated in my direct testimony, they always went beyond the industry standard.

Q. And was McCrone, this is Defense 8372. Was McCrone the only consultant that Johnson & Johnson asked to go beyond optical microscopy and do something else to try to evaluate whether Dr. Lewin was correct?

A. No. They had additional people look at it.

Q. Who else looked at it that way?

A. We covered this, but Dr. Fred Pooley.

Q. And what did he conclude about whether Dr. Lewin's findings were correct?

A. In the conclusions to be drawn from the examination are that no detectable chrysotile or amphibole asbestos is present in the Shower to Shower talc sample.

Q. And another document you were asked about, 'cause we've talked about a number of people who were consultants to Johnson & Johnson, but another document that the plaintiffs asked you about, I guess it's Plaintiffs' Exhibit 1297. And they asked you about this part about why Dr. Lewin

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was selected to do this initial work, right?
A. That's correct.
Q. Now, this document actually also discusses some other labs that looked at Dr. Lewin's findings and evaluated whether they were correct, so I want to point that out.
This is Dr. Schaffner writing. It says, "I've compared Dr. Lewin's results for chrysotile with those obtained for some of the same samples by four other laboratories. The additional two laboratories included in this part of the study are Columbia Scientific Industries of Austin, Texas who sell the stone apparatus for differential thermal analysis, and the health protection branch of the Department of National Health and Welfare of the Canadian Government in Ottawa.
"The agreement of results from different laboratories is much less satisfactory for chrysotile than discussed above for tremolite. For example, Samples 89 and 173 were found by Dr. Lewin to contain five and 10 percent of chrysotile, respectively, but chrysotile was not found in these samples by the other laboratories."
Do you see that?
A. Yeah. It was 163, but yes, I see

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that.
Q. 163.
So were there other outside labs that were not consultants to Johnson & Johnson that also disagreed with Dr. Lewin's findings?
A. They were not able to replicate them at those percentages, yes.
Q. Including the health branch, health protection branch of the Department of National Health and Welfare of the Canadian Government Ottawa, correct?
A. That was one of these entities they list here.
Q. We've looked at Defense 7058.
What did even Dr. Lewin say about Dr. Lewin's results?
A. I'm sorry?
Q. What did Dr. Lewin say about his own results?
A. I'm sorry. Is this -- can I see the whole thing here? I'm sorry. I'm not sure if this is --
Q. Well, if you can't read it enough, I'll skip it. It's already in evidence.
There was also a lot of discussion

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with the plaintiffs' counsel about Dr. Langer. And to put this in -- I do have the full copy. I'll give you a copy.
So now that we have a copy, I will go ahead and show the --
MR. PANATIER: Your Honor, I make a scope objection.
THE COURT: Sidebar. Bring that up.
MR. PANATIER: I got it.
(Sidebar.)
MR. DUBIN: Your Honor, he brought up Dr. Lewin and discussed all Dr. Lewin and whether the findings were right, whether there were proper procedures used in order to verify or not verify Dr. Lewin's results. And I'm simply asking about this document that's in evidence about Dr. Lewin saying that he himself wouldn't stand behind his results.
MR. PANATIER: It's outside the scope. I didn't do this. I discussed all of their testing. And, in fact, I went directly at what counsel did yesterday. I didn't bring up newspaper articles or anything.
THE COURT: I must be confused. You brought up newspaper articles with regard to --

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MR. PANATIER: Langer.
THE COURT: -- Langer years later.
This is permissible. I mean, it's within the scope. It just uses a document that you didn't use.
MR. PANATIER: All right.
THE COURT: It's on that issue.
Go ahead.
(Sidebar ends.)
BY MR. DUBIN:
Q. So we were just finishing off Dr. Lewin.
THE COURT: Can you just give a marking to that?
MR. DUBIN: This is Defense Exhibit 7058. This is just a full copy of it.
THE COURT: Okay. I see. Thank you.
MR. DUBIN: The full copy is in evidence.
BY MR. DUBIN:
Q. Even Dr. Lewin himself, what did he say about his results?
A. He says in the article referred to, "I was erroneously quoted as having reported that Johnson & Johnson's talcum powder contained two to

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three percent asbestos. In actual fact, I reported that of 11 samples of the products of this company, I found no evidence of asbestos in nine of the samples and the other two samples fell into the inconclusive category described above."

Q. And so you were also asked a lot about Dr. Langer, and you were shown a comment that he made in a newspaper article very recently.

But to start out with Dr. Langer, we did see an earlier newspaper article before, Defense 7032, that dates from the actual time around which he's doing his work. And what did even Dr. Langer say about Dr. Langer's work?

A. Well, I'm just going to read this.

"The data were very preliminary in nature and what is more, I may have mistaken long talcum fibers for asbestos fibers. They have similar properties, the doctor said."

Q. And we looked at another article previously. This was back again at the time, Defense Exhibit 8402. And what are they reporting back then about what Dr. Langer and Mount Sinai had found with regard to Johnson's Baby Powder and medicated powder?

A. It states, "The products that the

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researchers found uncontaminated with asbestos fibers were Ammens Medicated Powder; Avon Bird of Paradise Beauty Dust; Diaperene Medicated Body Powder; two Johnson's Baby Powders, one made here and one in Britain; Johnson's Medicated Powder; Mennen Bath Talc; Yardley Aftershave Powder and Yardley Original Body Powder."

Q. And again, rather than things in the newspaper, before we also looked at an actual published paper, Defense Exhibit 8096, where Dr. Langer and his colleagues at Mount Sinai published a paper about various talcum powder products that they looked for the presence of asbestos, right?

A. That's correct.

Q. Did they report any asbestos in any of the Johnson & Johnson products?

A. They did not.

Q. So then you were shown this comment from December of 2018, and that's many decades after the actual work was done?

A. This would be. Yes.

Q. And the comment you were shown is "In recent interview, Dr. Langer told The Times that Dr. Chalmers spoke for himself and not for the

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institution, not for our research group. He reiterated that his team had detected asbestos in Johnson's Baby Powder. I stand by that today. Absolutely."

Right? You were shown that?

A. I was.

Q. I want to talk about what that Dr. Chalmers thing is and what happened.

MR. PANATIER: Your Honor, we have to approach on scope.

THE COURT: Sure.

(Sidebar.)

MR. PLACITELLA: It may be unintentional, but every time Mr. Panatier makes an objection counsel should not be throwing his hands in front of the jury.

MR. DUBIN: You're right. I apologize.

THE COURT: You won't do that again.

MR. DUBIN: I won't.

THE COURT: After we finish Langer, we'll take the lunch break.

Your --

MR. PANATIER: My objection is that this is outside the scope. What they're going to do

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is they're now getting into, is that the press release?

THE COURT: Right, Chalmers.

MR. PANATIER: Right.

So the fact that he said that in order to, in order to read the full sentence, which it's one full sentence to talk about how Langer stands by his results, I had to read the full sentence.

But we didn't talk about the Chalmers press release. We didn't get into it at all.

THE COURT: It doesn't matter. You raised the issue. And what you read to the jury was Chalmers spoke for himself.

So by, going beyond the scope would be like a totally separate issue. This is the issue.

MR. PANATIER: It's -- okay. That's fine.

THE COURT: That's my ruling.

MR. PANATIER: I'll come back with the meeting where they met with her, that's fine.

THE COURT: You'll approach me first before you do that.

(Sidebar ends.)

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BY MR. DUBIN:
Q. So the reference to Dr. Chalmers, I want to make sure we understood what that was. This is Defense Exhibit 7506.
A. Do you have the full --
Q. (Handing.)
So, this was from the archives of Mount Sinai, the Office of the President and Dean, Thomas C. Chalmers, from back in 1976. And it's regarding "Recent media reports concerning research on talcum powder carried out by the Mount Sinai Medical Center created considerable confusion on the part of the public.
"The Medical Center has issued the following statement in order to correct any misinterpretations or mis-impressions that media reports may have given."
And then one of the things they go on to talk about --
A. I'm sorry, you're on page 3 of 7?
Q. I'm now going to page 2.
A. Page 2. Okay.
Q. Two of the things that they said, Dr. -- or Dr. Langer's institution, The Mount Sinai, it says, "Although the news media specifically

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emphasized the dangers of talcum powders advertised for babies, the only baby powder tested that was reported to show asbestos represents less than one percent of the market and that sample was five years old. The most commonly used baby talc has been consistently free of asbestos."
Do you see that?
A. I do.
Q. And do you understand that to be Johnson & Johnson?
A. I would -- I would make that assumption, yes.
Q. And the other thing that Mount Sinai wrote back in 1976 is, "It is the opinion of Mount Sinai's Department of Pediatrics that baby talc is a useful and safe product."
Do you see that?
A. I do.
Q. And then what we see on the next page in terms of why this was done, there's a memo --
A. I'm sorry. You're now on page 4 --
Q. I'm now on page 4 of 7.
There's a memo between a Dr. Irving Selikoff and Dr. Thomas Chalmers.
You see that?

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A. I do.
Q. And Dr. Chalmers writes, "I do feel that we should not be afraid to admit it when we have made a mistake."
Do you see that?
A. Yes, I do.
Q. And that was Dr. Langer's institution?
A. This is from Dr. Thomas Chalmers to Dr. Irving Selikoff, both at Mount Sinai at this time, I believe.
MR. DUBIN: Okay. I think it's time for a lunch break.
THE COURT: Members of the jury, we're going to take the lunch break now. Leave your notebooks here.
Remember the instructions I've provided: No discussions with regard to this case, including the testimony you've just heard. No research of any kind whatsoever.
Please be ready to come back upstairs at 1:25. Thank you. Enjoy your lunch. Wear your juror badges where they are visible. Thank you.
(Jury exits.)
THE COURT: We're off the record.

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(Luncheon recess taken from 12:22 p m. to 1:28 p.m.)
A F T E R N O O N S E S S I O N
COURT OFFICER: Jury's entering.
(Jury enters.)
THE COURT: Please be seated. Make sure cell phones are turned off
Mr. Dubin, whenever you're ready
Do you want us to go off the record?
MR. DUBIN: No. We're fine.
BY MR. DUBIN:
Q. Hi, Dr. Sanchez. How are you?
A. I'm well.
Q. So we left off talking about some of these boards, and again, I'm not going to go through all the ones that we went through yesterday, that plaintiffs' counsel didn't ask you, but again, there were a number of these entries where they say something like tremolite or amphibole, were those asbestos; in other words, things like the Battelle documents?
A. No, you have to look at the specific documents and what do they mean.
Q. So let's then move on.
I want to talk about some of the new

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documents that were shown to you today by the plaintiffs' counsel. And I'm going to start here. This was marked as Plaintiffs' Exhibit 3695-247. And to make sure we know what we're looking at here, there's a stamp on the bottom that says, "Imerys." And I don't think it's disputed, but that this is not a Johnson & Johnson document or a document from Johnson & Johnson's files, just to put that in context.

Do you see here one of the things they've noted is that this company, Imerys, has printed out some data regarding some old test results where, in something called Grade 96 composite, they've identified, in a couple tests, one chrysotile structure in those tests; right?

A. Correct.

Q. So I want to talk a little bit about the significance of finding or not finding one chrysotile structure in a test like this.

And we have sort of alluded to this yesterday when we talked about these standards about detection limits. Can you just describe again to the jury what a detection limit is and how it's used?

A. I'll try. It's somewhat of a

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difficult concept. I appreciate that.

When you're doing particle counts such as this bench sheet represents, the idea here is if you go through and you analyze and you don't see anything, meaning you have a zero count, there's a 95 probability if you go and analyze again you could see anywhere from nothing again up to three.

If you go in and you do an analysis and you see one particle, there's a 95 percent probability that you go back in and you will see no particles, or you could see one particle or two particles.

So as you go through and you look at the probability on the counts, up until you get to about three, assuming your background is completely clean, a count of one, if you are trying to reproduce that, you have a likelihood of getting nothing detected on your second round.

So because of that, it's in what I call the noise of the analysis. It's in the uncertainty of the measurement. So we use detection limits to ensure that whatever is being observed is above and can be distinguished from the zero count. That's all these methods are protecting against.

Q. And is that a common concept in

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methods used throughout the study of asbestos, including Government regulations and standards?

A. It is.

Q. Okay. And, in fact, we looked at this document, it cites to an ASTM standard. Do you see that, ASTM D?

A. I do.

Q. And first of all, what's the ASTM again, if you can remind the jury?

A. It's the American Standard and Testing -- and Materials, or I forget what it is exactly, something like that.

Q. And has the ASTM written about the purposes and significance of these kind of detection limits?

A. They do. They have a method specifically for the determination of detection limit based on counts.

Q. I want to look at that and see what the actual method says based on the significance of finding something like one chrysotile fiber. And I'm going to use this.

And I'm not going to introduce it, but do you want us to still assign a number to it?

THE COURT: Still assign a number to

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it.

MR. DUBIN: We'll call it S-7.

THE COURT: Thank you.

(S-7 was marked for identification.)

BY MR. DUBIN:

Q. Here we're looking at something by the ASTM called Standard Practice For Asbestos Detection Limit Based on Counts. Is this something you're familiar with?

A. I am.

Q. So we have here discussion of this idea of needing to find a certain amount of fibers for a positive. And one of the first things it discusses is just the general concept. And this is not something written by Johnson & Johnson, right?

A. Correct.

Q. What it says is, "The detection limit is one of a number of characteristics used to describe the expected performance of a measurement method. The DL concept addresses certain potential measurement interpretation errors. Specifically, a measurement is reported as being below the DL if the measurement cannot be distinguished from zero or from the randomly varying background contamination level."

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So can you describe what that part means? What does it mean that it's reported as below the DL if the measured level cannot be distinguished from zero or from the randomly varying background contamination level?

A. It's just what I described when you were with those very low counts, it's within just the analytical uncertainty of the measurement, you could analyze the same talc over and over again and never see anything again. So you can't establish that count of one from the background of zero.

So again, it just has to do with the counts. And again, it reflects the noise of the analysis or the uncertainty of the measurement.

Q. And what it says right after that is that "Stated differently, the DL provides protection against a false positive finding."

What does that mean?

A. A false positive finding is where asbestos is reported when it really is not there. So that's one of the reasons why DLs are used is to protect against the false positive finding.

Q. And these kind of findings that we see from the, even internal to the supplier about this one chrysotile structure here or there, how

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does that relate to the concept of detection limit?

A. Well, within D-6620, which we were just looking at, this is all within that noise of the analysis, and so when they're reporting out their concentrations it's less than whatever that DL is for that method that they're employing.

Q. So are all of these under the levels of detection limit that is intended to provide protection against the false positive finding?

A. Yes. They would be.

Q. Okay. And then another document that you looked at from the time period of Vermont was again an Imerys document. That was Plaintiffs' Exhibit 3695-248. Imerys, again this is an Imerys document, not a Johnson & Johnson document, right?

A. Correct.

Q. Okay. And do you know whether something like this would even have been shared with Johnson & Johnson?

A. I have no knowledge to that.

Q. Okay. But irrespective, this is somebody at the supplier at a company called Rio Tinto Minerals discussing an analysis of a fibrous material from Argonaut and it says, "A sample of acicular mineral material collected at the Argonaut

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mine was submitted for identification."

Do you see that?

A. I do.

Q. Is this, does this indicate anywhere that this is an analysis of a production run or sold talc or anything like that?

A. No. My recollection of other documents, this is dealing with a material they were looking at potentially using for road-based material.

Q. So does this even have anything to do with talc used in baby powder?

A. No. This has nothing to do directly with the production of a cosmetic grade talc in that deposit.

Q. And one of the interesting things I think we see here, do you see the way that they describe it. It says, "The sample was identified as asbestiform actinolite amphibole."

You see that?

A. I do.

Q. Does that indicate to you what we should -- now, you don't disagree that whatever they're analyzing here is asbestos, right?

A. No. It looks like an amphibole type

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asbestos.

Q. But when we're evaluating other documents that may just say actinolite or may say tremolite, does this help us understand what we should be seeing if people are really identifying asbestos?

A. If they're being specific in their usage of the terms, yes.

Q. And in many instances in many documents where we've seen just the word tremolite, does it have that qualifier saying that it's asbestiform?

A. No. They do not.

Q. Again, is this a positive finding of asbestos in Johnson & Johnson's Baby Powder?

A. No.

Q. Another thing you were shown are some more documents. We're trying to ask exactly what this is, but I think, was this -- anyway, we'll ask how it is, but it doesn't have any Bates stamp from anybody on this.

THE COURT: It does?

MR. DUBIN: It doesn't. I don't think so. It just has a plaintiffs' number.

THE COURT: It's a means of

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identification you can use if you're going to put it up there. I understand what you're saying in terms of a Bates number, but you have to use the identification number.

MR. DUBIN: I understand, your Honor. And again, we're working with plaintiffs' counsel in getting this.

MR. PANATIER: It's got a sticker on it.

THE COURT: I know.

MR. DUBIN: Fine. It has a plaintiffs' sticker on it, 3695-253. I believe we understand this is a printout of some spreadsheet, but anyway...

BY MR. DUBIN:

Q. It says, what it has here is it has, again, a finding of one chrysotile fiber back in January of 2003, and then they have something, I guess one, January 2001.

First of all, do you know whether Johnson & Johnson was even using Chinese talc at this time in 2001?

A. My understanding, they were not.

Q. Okay. So these kind of fibers, are we talking about the same thing where you find one

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stray chrysotile fiber in an analysis?

A. Again, they're applying the statistical uncertainty of the measurement for their detection limits, so one would be below their detection limit.

Q. Okay. And presumably if the supplier, and this is not -- if the supplier is doing analysis back here 2001, 2003, do you have an understanding of whether they continued to look at these kind of talcs for a long time thereafter?

A. I believe they -- yes. I have seen other testing records in those other years from the supplier.

Q. So if plaintiffs are coming to you with an indication of like one chrysotile fiber in 2001 and one in 2003, what does that suggest to you about whether they're really finding chrysotile from the ore in the product here?

A. Again, this is just suggesting whatever they're seeing, it's below the method's ability to really say what was there. You're still within that noise of the analysis.

Q. And then we see a number of other zeros and presumably others in different time periods, right?

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A. Correct.

Q. So finally, I want to get back to this idea of whether the testing boards we discussed were accurate. And you were asked about this document, the Crosetto ore document.

Do you recall that?

A. I do.

Q. It was talking about the mineralization of the general valley, right?

A. Correct.

Q. Again, we covered this yesterday. Is it different to say what kind of minerals are in a valley versus what are found in a part of an area like a mine that's being actually processed for consumer talc?

A. Yeah. I mean, what's being done here is he's saying, if you look at the geology of the whole valley, these are the things that we're finding potentially there, and then here's some samples from the talc mine itself, test those. So we need to look at the test results of the material.

Q. And in terms of the boards, you know, whether they're accurate or not, is there a lot of other testing that doesn't appear on the boards about talc used by Johnson & Johnson?

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A. Yes.

Q. And even in this specific instance about Crosetto, it says one drum of Italian rock, the actual -- was sent for analysis. And then we looked yesterday at Defense 7026 and when that was actually analyzed, what did the Colorado School of Mines report?

A. Again, it looks like they hand-picked through the bucket of rocks and the materials and they didn't find any amphibole serpentine phases; recognizes they were picking through it, and then also when they were running the powdered samples through the X-ray diffractometer they were also not detecting any amphibole or serpentine phases.

Q. And you were also asked by plaintiffs' counsel about this, again, about this Paoletti article, right?

A. Yes.

Q. And just to point out, first of all, they were talking here about and analyzing talcs used in that market, including various different industrial and cosmetic talcs, right?

A. Correct.

Q. And does it still, do you still have an opinion, sitting here today, whether anywhere in

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here they say they found asbestos in the talc that Johnson & Johnson was using -- is there more than one Italian talc?
A. It's not even saying that. It's saying they're purchasing talcum powders from the Italian market. You don't know the source of any of those products. They could be from Italy, they could be from other sources. All we know is they were purchased in Italy. We don't know anything about the provenance of the talcs being tested.
Q. Again, is there anything on this study that's on the board that said they tested Johnson & Johnson talc and found asbestos in it?
A. There's nothing in the document that says that.
Q. And, you know, as we walk through things in the boards, if you see, you know, an individual questioned issue in a particular document or another document, is it important to consider the evidence as a whole in terms of interpreting them and understanding them?
A. As much as you can, yes.
Q. Okay. And so, we talked about things like the board having Dr. Pooley's Italian on there. That was 7044. But we also know that, you know,

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when we saw, for example, something about Grade 66 or 96, which was Vermont, we looked at another document which was from Dr. Pooley about 7046; did he also do an analysis of the Vermont talc?
A. He did.
MR. PANATIER: Scope.
THE COURT: Sidebar.
(Sidebar.)
THE COURT: How is Pooley and Vermont raised on cross-examination?
MR. DUBIN: They're showing individual Grade 66 or 96 where he was crossed on finding. As Dr. Sanchez pointed out, understand things like that, whether they're really positive findings, also have to look at other evidence, the totality of the evidence and briefly pointing out what some of that totality of the evidence is.
THE COURT: Okay.
MR. DUBIN: To put it in context. I've only got a few slides left.
THE COURT: Thank you.
You wish to be heard on that?
MR. PANATIER: Sure.
I didn't get into Vermont stuff at all. And to try to gateway it by saying we have to

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consider the totality of the evidence, as counsel just said, it opens the door to the totality of the evidence.
MR. DUBIN: I'll withdraw my question, that's fine. I'll move on from Pooley. There's some (inaudible).
THE COURT: Thank you.
(Sidebar ends.)
BY MR. DUBIN:
Q. Okay. I won't belabor the point.
We did look at a number of other documents that are not listed on here about people's evaluation of Johnson & Johnson talc, right?
A. We did.
Q. And did that include some of the preeminent experts in the fields of microscopy and asbestos analysis?
A. At that time, yes.
Q. And as a final issue, I just want to ask you a few things.
One of the things that you were asked about was the amount of material that you can test by TEM and whether it's a breath mint or something else. First, I know you seem like you were trying to clarify something about weight, but I'm not sure

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what that was.
A. Well, if you're calculating out a structures per gram, which is what we're dealing with, you're always dealing with a mass. So I was just trying to clarify that when the conversation was being confused of only particles by particles.
Q. Okay. And when we talk about the idea that you can only look at a small amount of material by weight in TEM, what does that have to do with?
A. It's limitations of that technique. It's by nature of how high a magnification it is, you only ever can look at very small amounts of material and only very small particles just by nature of what it is.
Q. But when you're looking at that small amount of material, can you get down still to a very, very low level of sensitivity in terms of being able to detect something?
A. Yes.
Q. Like approximately how low are we talking about here?
A. Again, it depends on the analysis. You have to look at the amount of material, how it was prepared in order to arrive at it, but you're

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generally in the parts per million or parts per billion range.
Q. And because of that limitation of TEM, what do you then do when you're evaluating talc in order to try to look at a larger amount of material?
A. Well, this goes back to the approach of looking at the material in the mine itself, using powder X-ray diffraction is looking at two grams of material per test. And all these things that you're sampling, again, you're trying to sample these things in a way that's representative of larger material and you extrapolate out to the larger material.
But, again, you use X-ray diffraction, you use polarized light microscopy and you use TEM. You use those things all in conjunction.
Q. I guess you're making a good point.
Let's just focus on the microscope part first, or machine. Are there other types of analysis besides the transmission electron microscope that Johnson & Johnson has used that will allow you to look at a larger amount of material?
A. Yes.

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Q. Which are those?
A. One of those would be polarizing light microscopy. Another one is powder X-ray diffraction.
Q. And then if you want to take a step back and no longer be just looking at something zoomed in under a microscope, are there other ways that you can evaluate a mine or deposit or areas within it to determine whether it's likely to have asbestos?
A. Yes. If you can actually go and look at the rock before it's turned into a powder you can see whether there's veins of asbestos in the material before it ever would be processed. You can evaluate things of that nature in the field.
Q. Is that something Johnson & Johnson also did?
A. That is. Yes, they did.
Q. And finally, you were asked a little bit about money, and I just wanted to make it clear, as part of the work you've done that your company has been compensated for, you know, can you give the jury a sense of the volume and number of documents that you've reviewed to satisfy yourself about your opinions?

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A. Thousands of pages of documents, looking into the older techniques of the time. Again, when I'm reading the documents, where I can, especially with the testing methodologies through time as they have changed and again, some of the uncertainty in the early '70s I was discussing, actually looking at the documents for what they were doing in their methodology, and then to evaluate, by following that methodology, could you actually arrive at a scientifically supportable conclusion asbestos was present.
So again, you look into that, you look at the properties they're measuring and take that into account.
Q. And again, we're not going to talk about the substance of it given where we are in the trial, but again, can you give the jury a sense of the volume of work that has been conducted by you or at your direction at RJ Lee to look back at historical samples of Johnson & Johnson products?
MR. PANATIER: Sidebar, your Honor.
THE COURT: Sidebar.
(Sidebar.)
MR. PANATIER: They're trying to get the fact that he's done testing. And he kind of did

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this already in -- first of all, this is outside the scope.
Second of all, when they started yesterday they kind of squeezed this in where he said, oh, I tested Johnson & Johnson, I stand by my results. This is another opportunity for him to say that. I think that goes way too far.
MR. DUBIN: The one I asked him about when he said he stands by his results was outside litigation testing. He went through the exact dollar numbers that he's been paid in all of these cases where you know that what he was doing in part was generating gigantic reports, doing analyses, responding to Dr. Longo. How can I not at least say, you know, we're not just giving him free money and that he's actually worked for it like he's done with the analysis.
MR. PANATIER: I think it's perfectly fine to say have you been paid for testing. That's it. We're talking about historical samples, say that is, they're trying to get that in however they can. And he did it yesterday. He actually was asked about not just Johnson & Johnson samples, about historical tests. And he said we stand by our results. Ask him if he's done testing and if they

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got paid for it.
MR. DUBIN: Your Honor, again, I think once you get into a dollar number, how can I not ask how much work did you do for that? But I leave it to your Honor. I'm not going to continue to argue it.
THE COURT: How much work he's done is fine. Do not ask any question to elicit the results of his tests.
MR. DUBIN: I'm going to remind him again, as I tried to do in the preface, and I'm going to say --
THE COURT: I think it's a little bit better than yesterday, so thank you for chatting with him, but let's wrap this up.
I agree it's important in terms of, to counter the issue of payment, work that he has done, but no results.
MR. DUBIN: Okay. I'll try to remind him of that in preface in my question.
THE COURT: Yes. Thank you.
(Sidebar ends.)
BY MR. DUBIN:
Q. Where this trial is now we're not talking about results. We're just, you know, just

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in terms of you were asked about the amount of money that has been paid to the company, so I want to ask about the volume of work that you've done, you know, at RJ Lee, what the compensation for it is in terms of analyzing how many historical samples and the volume of reports and materials that have been prepared.
A. Yeah. Not speaking of any results of that testing, but again, we have tested over a hundred samples directly tied to the litigation. We have examined the documents. We have done many hours of literature search trying to understand the science of the time.
There's a lot of data that comes in from plaintiffs' experts that we need to evaluate. Every time there's a diffraction pattern we have to go in there and make measurements and match those measurements up to try to verify the findings. So there has been a lot of work done.
Q. Okay. And so if we end where we started, just to make clear, if we look at the evidence that you discussed with us and with plaintiffs' counsel, did Johnson & Johnson hire a number of prominent experts to look at its talc?
A. They did.

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Q. And did many of those experts report to Johnson & Johnson that there was no asbestos?
A. They did.
Q. And were there also Government findings and investigations that had reported that there was no asbestos in Johnson & Johnson's talc?
A. There were.
MR. DUBIN: Okay. Thank you very much.
THE COURT: Sidebar with regard to any proposed recross. Thank you.
(Sidebar.)
THE COURT: What are you seeking to do by way of recross and how do you think it's appropriate?
MR. PANATIER: Yes, your Honor.
The 2008 report from Argonaut, he said that was for road material. That's incorrect.
THE COURT: Right.
MR. PANATIER: This one is. So I need to straighten that out.
THE COURT: Okay. I'll allow that.
MR. PANATIER: The Chalmers, the press release.
THE COURT: Yes.

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MR. PANATIER: So I have the Johnson & Johnson memo about their meeting with Chalmers.
THE COURT: That's fine.
MR. PANATIER: And then lastly, he brought up the detection --
THE COURT: ASTM.
MR. PANATIER: ASTM. I'm just going to ask a question about that in relation to this.
THE COURT: About the ASTM?
MR. PANATIER: Yes.
THE COURT: Okay.
MR. DUBIN: Your Honor --
THE COURT: You get the final.
MR. DUBIN: No, it's fine. I'm trying to explain the reason for confusion, I guess, one of the documents seems to be a printout of part of a spreadsheet, so I don't know whether we have the -- he sent it to me now. We may seek to introduce an additional part of that when he's off the stand. I don't know, having not looked at the whole thing.
MR. PANATIER: You have it as it was produced to us by Imerys.
MR. DUBIN: I get it. I'll take a look at that.

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THE COURT: All right. Go ahead.
(Sidebar ends.)
THE COURT: Mr. Panatier, whenever you're ready.
MR. PANATIER: Thank you, your Honor.
RECROSS-EXAMINATION BY MR. PANATIER:
Q. All right. Dr. Sanchez, just a few things.
By way of example, we look at these results, right; you talked about that for every lab they have to determine and under that method, that ASTM method, they have to determine what the background is for that lab, correct?
A. That is correct.
Q. And do you know what the background is for the lab that did this work?
A. Again, I believe that they have a zero background level, which still encompasses counts up to three.
Q. They have a zero background level, right?
A. Based upon how you determine that, yes.
THE COURT: For the record, that was what document?

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MR. PANATIER: 3695-247.
THE COURT: Thank you.
BY MR. PANATIER:
Q. They have objectively, when they report chrysotile findings, someone is seeing the actual asbestos in the sample, they are measuring it and analyzing it, correct?
A. They saw something that they identified as chrysotile, yes.
Q. That's right.
You're not saying that it's some imaginary hypothesis, they actually saw the fiber?
A. Correct. That is why something is counted.
Q. You were asked about -- you were asked about a press release that Mount Sinai put out on March 23rd, 1976.
Do you recall that?
A. I do.
Q. Now, sir, you know the day before Mount Sinai issued that press release, five employees were in the offices at Mount Sinai, correct?
A. I don't know the number, but I believe I have seen that document.

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Q. Well, this is Exhibit 3049. It's in evidence. And we can, if we need to, we can count the folks, 'cause it says here on March 22nd, 1976.
Now, the press release goes out the next day, right?
A. I believe that's correct.
Q. Okay. A meeting was held with Dr. Thomas Chalmers, and he's the one that issued the press release, correct?
A. Correct.
Q. President of the Mount Sinai School of Medicine. Dr. S.D. Pomrinse, that's an interesting name, Pomrinse of the medical school and Mr. Samuel Rovner, I got it, someone's trying to tell me to highlight.
Let's see, Johnson & Johnson was represented by Mr. D.D. Johnston, Mr. J.E. Burke, D.D. Petterson, Mr. L. Foster and Mr. Gavin Hildick-Smith; one, two, three, four, five people, right?
A. That's correct.
Q. Now, at the time, were you aware that D.D. Johnston was the president of the Baby Products Company?
A. I don't know what these people's

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positions are.
Q. We've got five people from Johnson & Johnson showing up in the offices, right?
A. Correct.
Q. This is a Johnson & Johnson memo about that meeting, correct?
A. Yes, I believe that's correct.
Q. The object of the meeting was to review with the Mount Sinai school management the need for a statement from them correcting the record in the press to indicate that baby talc is safe, the samples of talc assayed by the Selikoff group were at least three years old and that nickel containing talc was not a hazard.
Now, they put out an article, they wrote a literature article that came out in 1976, correct?
A. Who did? I'm sorry.
Q. Mount Sinai.
A. Some individuals from Mount Sinai. Yes.
Q. Right. Okay.
So Johnson & Johnson is saying that they need to issue a statement about that, correct?
A. I'm not sure what they're referring

to here. It sounds like this is a press release that they're looking into, not an article.

Q. Okay. All right. That's fine. That's fine.

"Initially, Dr. Chalmers, who had clearly given a lot of thought to the issue, suggested that it might be wisest if all parties forgot the whole incident and that nothing would be gained by obtaining a retraction from the Mount Sinai medical school. It was pointed out that a follow-up story in the media and press would have less impact than the initial story.

"Johnson & Johnson representatives, however, clearly expressed their desire to have a retraction statement not only to allay the fears of many anxious parents, but to correct the record concerning the safety of baby talc and the fact that Mount Sinai scientists had failed to report that the samples studied were at least three years old."

So they wanted a retraction and one of the things they say is to allay the fears of parents, right?

A. You read the document. That's what it says.

Q. "The Mount Sinai group indicated that

over the weekend the Selikoff group had been studying six new samples of talc and had reported that all of them contained minimal amounts of asbestos. The Mount Sinai management thought that this information should be in the retraction statement, but the Johnson & Johnson group assured the Mount Sinai management that such a statement should be avoided in case it turns out that it was wrong." Right?

A. Yes.

Q. So Mount Sinai, they show up in the offices. Mount Sinai said we did some work over the weekend, six more samples all contain asbestos. Johnson & Johnson says no, you might be wrong, so you shouldn't include those in the retraction, right?

A. I would agree that you shouldn't be reporting findings if they're not verified.

Q. Well, they didn't say they weren't verified. Johnson & Johnson says you could be in error, so you shouldn't include them. That's all we know from this. Isn't that true?

(Continuation of the day's proceedings in Volume 2.)

CERTIFICATION

I, ANDREA F. NOCKS, C.S.R., License Number 30XI00157300, a Certified Court Reporter in and for the State of New Jersey, do hereby certify the foregoing to be prepared in full compliance with the current Transcript Format for Judicial Proceedings and is a true and accurate non-compressed transcript to the best of my knowledge and ability.

Andrea Nocks CCR CRR

ANDREA F. NOCKS JANUARY 29, 2020
CERTIFIED COURT REPORTER
MIDDLESEX COUNTY COURTHOUSE

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Exhibit 164

Date	Exhibit #	Testing Entity	Author	Recipients	Purpose Stated	Test method	Mine	What was tested	Special Preperation	What tests revealed	Hopkins Comments	Satisfies J&J Asbestos Defin
10/15/1957	J&J-309	Battelle	Smith					Italian talc		" the Italian talc averages about 10% fibrous or acicular particles"		
5/9/1958	J&J-1	Battelle	Smith	Dr. Lycan		petrograph	Val Chisone	processed talc Italian 1		tremolite		
5/29/1958	J&J-2	Battelle	Smith	Dr. Lycan		microscope	Val Chisone	processed talc-italian 1		tremolite; 6 to 10 % fibrous talc		
12/4/1970	J&J-9	Colorado School of Mines	Colorado School of Mines	Miller		XRD & petrograph	Hammondsville	38 core samples		tremolite-actinolite; fibrous talc		
3/9/1971	J&J-257	McCrone	Grieger	Goudie		SAED; XRD		Shower to Shower; medicated powder		"fiber of chrysotile.. Was very clear"; "medicated powder we found one fiber of chrysotile"; Shower to Shower...we feel stronglythat it may be chrysotile...chrysotile is very low"; >>> Final Report >>>"Shower to Shower The fiber content of Shower to Shower is quite low in comparison to previous samples which we have investigated...We found three suspect fibers . Of these, two were found in one field and probably have the same source, very possibly contamination...It is still questionable whether they are chrysotile. We have, however, found traces of chrysotile in G-11 one of the additives to Shower to Shower , and this might be a possible source of these contaminant fibers."		YES
5/14/1971	J&J-255	J&J	Ashton	Smith		XRD		Baby Powder (production batch)		tremolite; tremolite-actinolite		
7/2/1971	J&J-256	Colorado School of Mines	Pattengill	Ashton		XRD; PLM		six monthly plant run samples		5 of 6 show tremolite-actinolite; "no other forms of nontalc minerals approaching asbestos types were indentified"		
7/7/1971	J&J-15	Colorado School of Mines	Pattengill	Ashton		XRD	Vermont talc	processed talc-344-L		tremolite & actinolite		
7/29/1971	J&J-19	Colorado School of Mines, McCrone, Dartmouth	Nashed	Foster			Vermont talc			"trace amounts of fibrous minerals; (tremolite/actinolite) "		
10/12/1971	J&J-23	McCrone	Grieger	Goudie	appearance and fiber content	electron diffraction		Shower to Shower		traces of chrysotile in one of additives		YES
11/11/1971	J&J-376	McCrone	Grieger	Goudie		TEM		Shower to Shower		"The Shower to Shower appeared to have a few more fibers than the other two samples ,however I think that mightbe due to possible contamination from the G-11..in the G-11 we did findtwo positively identified chrysotile fibers and some other fibers which at first glance peared to be chrysotile, when you look atthe electron diffraction pattern. I believe that most of the fibers in Showerto Shower which are suspectmay come from G-11....I left out the comments on G-11from the report becuase I felt you mightwant to change your supplier or investigate your supplier , and this would only tend to confuse the issue perhapswith the FDA."		

EXHIBIT
Hopkins-28
Date: 11-5-18
MLG, CSR, RPR, CRR

EXHIBIT
J&J-414

8/3/1972	J&J-28	NYU	Seymour Lewin	Dr. Weissler (FDA)		XRD		Shower to Shower sample 84		5% chrysotile;		YES
8/10/1972	J&J-373	J&J				PLM		Shower to Shower		"About 1 fiber or rod/needle every 500 particles. Approx. 1/3 of these are tremolite		
8/24/1972	J&J-29	Sperry Rand	Nashed	Dr. R. A. Fuller	FDA submits Lewin sample	SEM		Shower to Shower		"asbestos fibers could be detected in the sample"; "reported chrysotile"		YES
8/31/1972	J&J-348	Sperry Rand	JJ Wehrung			SEM		Shower to Shower		Dr. Weissler used SEM "to study general shape of chrysotile asbestos." "Dr. Weissler he did find fibers which had the general shape of chrysotile". Also found "asbestos form fibers" in samples brought by JJ which were photographed."		
9/8/1972	D-7	Sperry Rand	JJ Wehrung			SEM		Shower to Shower		Observation of asbestosform "more correctly be called fiberform". SEM "very able to identify fiberforms which may be chrysotile"		
9/26/1972	J&J-31	Dr. Lewin	Dr. Nashed	Dr Fuller				J&J Medicated Powder; Johnson's Baby Powder; J&J Shower to Shower		Medicated Powder: tremolite 4% Baby Powder: 2-3% chrysotile Shower to Shower: 2-5% chrysotile		YES
10/27/1972	J&J-36,34,37	McCrone	Stewart	Goudie	"the presence of asbestiform minerals"	XRD; TEM		Johnson's Baby Powder batch # 108T &109T (Lewin Samples)		"Both samples contained an insignificant amount of tremolite;" tremolite rods		YES
2/26/1973	J&J-100	Colorado School of Mines	Reid	Ashton	mineralogy & occurrence of any asbestos type minerals	XRD		processed talc	centrifuging	tremolite-actinolite; slight trace of anthophillite? Chrysotile? "asbestos type materials"		YES?
4/26/1973	J&J-44	J&J	Petterson	Johnston		PLM	Hammondsville	Johnson's Baby Powder		"tremolite or actinolite are indentifiable (optical microscope)and these might be classified as asbestos fiber"		No
4/27/1973	J&J-335	J&J				optical microscope		Johnson's Baby Powder		trace amounts of amphiboles in all samples. "The optical properties of the aprticles are closer to actinolite than tremolite"		
5/1/1973	J&J-367		Miller	Petterson			Haamondsville	ore		"the orde body contains tremolite"	Doesn't say which mine	
5/8/1973	J&J-368	J&J		Petterson			Hammondsville	ore		"Your question this morning was how did Lewin assay timing relate to actinolite showings. Baby Powder lots 108T & 109T were alleged to contain asbestiforms by Lewin. Talc shipments checked by microscope here showed all lots clean just prior to and right after that time. the first showing of actinolite we know about is October 1972. The indications are that things were in good shape when Lewin picked up the above two lots for his assays."		
6/6/1973	J&J-47	Cardiff	Pooley	Ashton				our Vermont talc	concentration technique	actinolite		
9/6/1973	J&J-258	FDA	Stuart		"determination of asbestos	XRD; PLM		Shower to Shower sample 84		"fibers of tremolite/actinolite"		Yes
12/21/1973	J&J-263	Colorado School of Mines	Reid	Ashton	"examined for chrysotile and/or tremolite	TEM		Vermont talc samples	centrifuge	"identified chrysotile at a level of less than 10 ppm in the Vermont sample"		Yes

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1/29/1974	J&J-57	McGrone; Dartmouth		Lee		TEM; XRD	Hammondsville	ore & product		"chrysotile fiber suppression was indicated"; Dartmouth finds amphibole 100 to 200 ppm in ore and 3000 in ore; Mccrone finds chrysotile in ore and finished product		Yes
Mar-74	J&J-58	Dartmouth	Reynolds	Windsor Minerals	develop methods for measuring the concentration of asbestiform amphiboles"	XRD & XRF	talc product & ore from Windsor	ore & product	centrifuge to float talc and settle denser materials	"ore sample contains 2300ppm actinolite and the talc product contains 170 ppm actinolite"; "small amounts of anthophyllite may be present"	Dr. Hopkins has issues with the conclusions.	
4/24/1974	J&J-65	McCrone	Stewart	Zeitz	determine "whether or not there was any significant content of asbestiform minerals "	XRD; TEM	Argonaut	ore		TEM finds chrysotile and fibrous tremolite		Yes
5/8/1974	J&J-66	McCrone				opticcal microscope & TEM		Windsor 66 ore & product		ore-fiber probably tremolite & chrysotile; product- one chrysotile fiber	Possible contamination of 1 test	YES
5/9/1974	J&J-366	McCrone				TEM	Argonaut	ore & product		chrysotile fibers in ore and product of 1/3 of samples tested		
5/14/1974	J&J-370	McCrone, Dartmouth	Zeitz			TEM	Hammondsville	Windsor 66 ore & product		Table 15 McCrone Summary-probable chrysotile in 2 samples and chrysotile in 2 other samples. >>>Attachment A Dated 05-08-74>>>>>>> "Sample 66-AC ore showed chrysotile fibers but in the product from the same ore benefaction had reduced the chrysotile content to 1 fibril as mentioned above. The chrysotile fiber content of Sample 66-AC-ore represents an estimated chrysotile content of<1-2 ppm, thus, even in the worst case, the level of asbestos contamination present in these ores is minimal."<<<<<<<<<<Attachment B>>>>>>>>>"fibrous form of anthophylite which occurs as a rare mineral in the Hammondsville ore body."		
10/10/1974	J&J-74	McCrone	Shimps	Zeitz	analysis for "asbestisform fibers"			product		"fibrous asbestisform material" "chrysotile fibers were found"		YES
7/1/1975	J&J-89	McCrone	Grieger	Zeitz	"determine the extent of amphibole or serpentine contamination" "we kept a running tabulation of the asbestos we could possibly identify"	TEM, SAED		"from your ore body"		"confirmed asbestos" low to medium, "bundles of amphiboles"		YES
9/9/1975	J&J-92	Mt. Sinai	Langer			TEM; PLM, XRD		Johnson's Baby Powder		anthophyllite & tremolite		
11/5/1975	J&J-97	McCrone	Grieger	Zeitz	supplement report of 7-01-75	TEM		ore		Table 1 lists "fibers of asbestos"		YES

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1/25/1977	J&J-141	Gardiff	Pooley			XRD		Vermont composite sample		fibers of antigorite		
6/14/1977	J&J -246	EMV				SEM; XRD		ore & product		composite samples-large and small fibrous tremolite	Source unknown-- Mr. Bicks says look in Metadata	YES?
2/9/1979	J&J-164	George Lee's Group	Cohen					66 composite samples		tremolite & actinolite		
9/1/1983	J&J-175	McCrone	Palenik	Miller	"airborne fiber concentrations"	NIOSH method	Argonaut; Rainbow	air samples		Argonaut - 118 fibers; Rainbow- 2650 fibers	Type of fiber not specified	YES
11/2/1984	J&J-179	McCrone	Palenik	Miller	"analysis for asbestos"	TEM- EPA method		air samples		5,600 to 60,000 chrysotile asbestos fibers All samples found asbestos		YES
5/15/1985	J&J-177	MSHA	Olson		analysis for "asbestisform minerals"	PLM; XRD	Italian talc	air samples at Cyprus South Plainfield		71.2% fibrous talc & "5.8% anthophyllite, an asbestiform amphibole"		YES
8/5/1986	J&J-184	McCrone	Laubenthal	Miller		PCM	Hammondsville	air samples		fibers in both samples	Type of fiber not specified	YES
3/30/1987	J&J-185	J&J	Schmidt	Miller			Raymond Mill	Processed talc		"Tremolite is present in the fines (minus 100 plus 200 mesh) in six volume percent as free needles"		
4/15/1988	J&J-190	Skyline Laboratories, Aquatec Environmental				XRD	Chester/Hamm	random and composite process samples		actinolite		
2/25/1992	J&J-202	Cyprus	Munro				Argonaut; Hammonsdville; Black Bear	ore		"fibrous tremolite was identified...in exposures and cores at the east Argonaut 7 Black Bear mines. Cyprus staff report past tremolite from the Hammondsville and Clifton depositis."		
0/00/0000	J&J-298	McCrone						Windsor grade 36		chrysotile		
02/09/1979	J&J-341	J&J	Lee					Windsor 66 composite sample		"massive amphiboles in the 66 composite sample of Nov 6-10. the sample was forwarded to George Lee's group where the present of amphiboles was confirmed. They were identified as tremolite & actinolite"	duplicate of J&J 164	
05/09/1958	J&J-311	Battelle	Smith	J&J		Petrograph	Italian talc			"acicular and fibrous particles of talc", the 8 to 10% of nonplaty talc is presumed to be derived from tremolite or enstatite"		
1/12/1984	J&J-305	McCrone	Palenik	Miller		PLM	Talc powder, grade EV			actinolite The tremolite-actnolite in the sample is considered to be asbestos by current government regulations, however, it appeared to be cleavage fragments of the massive form rather than true asbestiform. typical tremolite fibers		
1/24/1958	J&J-310	Battelle	Brown	Lycan J&J			Italian talc			3 to 10% non platy with trace amounts of tremolite		
4/19/1973	J&J-296	J&J	Hamer			Dispersion staining	Johnson's Baby Powder			* four of the samples are suspected of containing tremolite based on the finding of one or two "fibers" per sample which satisfy the color/morphology criteria."		

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4/27/1973	J&J-335	J&J				Petrographic optical microscope		Johnson's Baby Powder		"trace amounts of amphibole" in all 4 samples tested; "Shape- prismatic, columnar, parallel – sided rods" ; Size: from 20X4 microns to 200X30 microns.; Indentity : the optical properties of the particles are closer to actinolite than tremolite"		
7/05/1976	J&J- 303	Colorado School of Mines				optical microscope		Johnson's Baby Powder		"small (1%?) amounts of amphibole needles."		
8/09/1972	J&J-342	J&J						Shower to Shower		"trace tremolite" in 1970 and 1971 samples	No chrysotile observed	
8/27/1973	J&J-299	Dutch consumer organization				electron microscope (REM)		Johnson's Baby Powder		" asbestos – content of 1.59%"		
9/11/1975	J&J-297	McCrone	Stewart	Zeltz				A-HC		chrysotile fiber	Plate 4682 A-HC 51,000X Chrysotile fiber	
9/18/1961	J&J-313	Battelle	Smith	Ashton		petrograph		Hammondsville core		2 percent non platy talc in upper core; 14% (granular and fibrous) non platy talc with 1-2% altered amphiboles in lower core		
??/??/????		Dutch Consumers						Johnson's Baby Powder		claimed to have found asbestos		
??/??/1972	J&J-33	University of Minnesota			determine possible content of fibrous chrysotile asbesots	TEM		Shower to Shower		"chrysotile asbestos does exist in the specimens of shower to shower"		
0/00/1991	J&J-327	Cypress	Munro				Argonaut mine			"Argonaut:main ore body open pit ..high incidence of fibre bearing zones encountered in the main ore body"		
0/00/1991	J&J-327	Cypress	Munro				Hamm mine;			"areas with fibrous actinolite"		
7/9/??	J&J-17	Mt. Sinai	J&J			electron microscopy		Johnson's Baby Powder		chrysotile asbestos		
10/27/1972	J&J-26	J&J	Nashed	Goudie				Johnson's Baby Powder batch # 108T &109T (Lewin Samples)		"There are trace quantities (tremolite) present confirmed both by McCrone & BillAshton Levels are extremely lawbut occassionally can be seen optically. This is not new."		

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Exhibit 165

The Cosmetic, Toiletry and Fragrance Association, Inc.

1133 15th STREET, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

March 15th, 1976

Mr. Heinz J. Eiermann
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

On March 11th, 1976, Mr. Eiermann --

-- the CTFA Talc Subcommittee met to discuss the current status of talc. It was recognized that a need exists to bring to your attention a profile of the analyses for asbestos form materials in talc used in the U.S. production of cosmetics and toiletry products.

The attached letters demonstrate responsibility of industry in monitoring its talcs. We are certain that the summary will give you assurance as to the freedom from contamination by asbestos form materials of cosmetic talc products.

Individual companies are more than willing to discuss the detailed data with you at your convenience.

Cordially,

Norman F. Estrin, Ph.D.
Vice President - Science

NFE:jj
Attachments

Exhibit 166

Johnson & Johnson

BABY PRODUCTS COMPANY NEW BRUNSWICK, N. J. 08903

March 15, 1976

Dr. Norman F. Estrin
Vice President - Science
Cosmetic, Toiletries, and
Fragrance Association
1133 15th Street, N.W.
Washington, D.C. 20005

Re: Examination for Asbestos In Talc

Dear Dr. Estrin:

The talc which is used by Johnson & Johnson is solely derived from its own mine in Vermont, where the ore is mined selectively and then beneficiated by the process of flotation.

Shipments of this highly purified talc are routinely examined by our own laboratory to verify the absence of asbestos minerals.

Historically, Johnson & Johnson has always been concerned about the mineralogical integrity of its talcs and even its earliest specifications have required the examination for acicular particulates. When it was erroneously reported in 1971 that our powder contained asbestos, we sponsored a scientific seminar of mineralogical and analytical experts for the FDA to prove that our talc is not contaminated with asbestos. At that time numerous samples were analyzed by experienced consultants such as McCrone Associates, Colorado School of Mines, Professor F. D. Pooley (of the University College, Cardiff), Professor G. Brown (of Princeton), and Professor M. Buerger (of M.I.T.). These examinations included X-ray diffraction analysis, differential thermal analysis, and transmission electron microscopy.

During the period December 1972 to October 1973, 93 lots were individually sampled and examined by X-ray diffractometry for the presence of asbestos minerals. No amphiboles or serpentine minerals were detected in any sample.

Beginning in October 1973, differential thermal analysis was added to our specified requirement. Both, differential thermal analysis and X-ray diffractometry were instituted for the routine examination of sequential lots. A further 100 lots have since been examined, applying both methods to each sample. Again, no amphibole or serpentine minerals have been detected.

I would like to advise that we are continuing to employ differential thermal analysis and X-ray diffractometry in the examination of sequential lots for the detection of amphibole and serpentine minerals.

It should be pointed out that we also maintain a worldwide monitoring of talcs used by our Johnson & Johnson affiliates, employing these same techniques.

Finally, let me add that periodically, we also submit sub-samples for Transmission Electron Microscope examination and these have always verified the absence of asbestiform minerals.

It is our understanding that you would wish to submit this information to the FDA. Please regard this letter as non-confidential.

Sincerely yours,

George Lee
Director of Applied Research

GL/mm

Exhibit 167

The Cosmetic, Toiletry and Fragrance Association, Inc.

1133 15th STREET, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

TALC SUBCOMMITTEE

M I N U T E S

A meeting of the Talc Subcommittee was held on March 31, 1976, at Bristol-Myers, 225 Long Avenue, Hillside, New Jersey. Those in attendance were:

George Sandland, Bristol-Myers (CHAIRMAN)
John Clements, Pfizer, Inc.
Christopher Costello, Colgate-Palmolive
John Facq, Colgate-Palmolive
Allan Harvey, R.T. Vanderbilt Co., Inc.
George Lee, Johnson & Johnson
Ray Krammes, Whittaker, Clark & Daniels
Roderick Mundy, Sterling Drug Inc.
Louis Murino, Cyprus Industrial Minerals
Fred Roesch, Whittaker, Clark & Daniels
Robert Rolle, Johnson & Johnson
Joseph Simko, Colgate-Palmolive
Terry Smith, Faberge
Harold Stanley, Charles Pfizer Co.
Ian Stewart, Walter C. McCrone Assoc., Inc.
Robert Suffis, Mennen Co.
John Travers, Avon Products, Inc.
Ronald Yakupcin, Kolmar Labs.
Norman Estrin, CTFA

Mr. Sandland opened the meeting and proceeded with the agenda.

1. Collaborative Study

Mr. Lee and Dr. Rolle updated the Subcommittee on reports of recent gathering of samples by the Mt. Sinai group. A suggestion was made that individual companies write directly to Mt. Sinai's management on the lack of creditability of Dr. Langer's results when applied to their specific products.

The advantages and disadvantages were discussed in detail of engaging in a collaborative study. It was generally felt the study could not be successful if there are restrictions on which talcs can be gathered. Many members favored engaging a collaborative study. Dr. Estrin suggested a proposal be put together to be presented to the CTFA Board of Directors (as was done in the case of the microbiological contents study several years ago). A subcommittee was organized to draw up this proposal consisting of Mr. Suffis, Mr. Lee and chaired by Mr. Sandland.

2. Periodic Reporting

The Subcommittee agreed on the success of the presentation of summary reports given to the FDA. Dr. Estrin suggested the Subcommittee should not obligate itself to give periodic reports to FDA but urged members to build their data base so that at some time in the future the Subcommittee can decide whether the time is right to present FDA with an update on industry analysis.

3. Review of Talc

The planned review of talc by the Miscellaneous OTC Drug Panel was noted. It was suggested CTFA begin at once to plan for a presentation to be made by a panel of experts, including independent experts, talc suppliers and manufacturers. The actual data for consideration by the Miscellaenous Panel of summary information on talc was not known.

5. Animal Studies

Dr. Estrin suggested consideration be given to planning animal studies on talc which may not be covered adequately by previous studies. Dr. Travers, Mr. Roesch and Mr. Lee will coordinate activities involving Dr. Gressel and Dr. Finkelstein to investigate this possibility.

6. Sampling

The Subcommittee agreed CTFA should not address the issue raised by Mr. Eiermann and Dr. Schaffner further with the FDA.

There being no further business, the meeting adjourned.

Norman F. Estrin, Ph.D.
Vice President - Science

NFE:mp

Exhibit 168

George Lee
Talc Committee - CTFA

Johnson & Johnson

C O N F I D E N T I A L

DOMESTIC OPERATING COMPANY NEW BRUNSWICK, N. J.

March 1, 1978

Mr. Charles Haynes
The Cosmetic, Toiletry and Fragrance Association, Inc.
1133 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Haynes:

I am enclosing a table which breaks the code for the recently completed CTFA Task Force on Round Robin Testing of Consumer Talcum Products for Asbestiform Amphibole Minerals. The names, addresses, and phone numbers are also included for those industrial participants whose products were involved.

In accordance with your discussions with Norm Estrin and George Sandland, Chairman CTFA Talc Subcommittee, we would request your assistance in the dissemination of these round robin results as follows:

1. Please contact me (201/524/5518) upon receipt of this letter so that I may destroy the only other copy of this table, which is in my possession.

2. Contact each of the industrial participants to inform them of the round robin results for their product only, as well as the actual lot tested. Please emphasize that no talcum product failed CTFA Method J4-1, Parts I and II; i.e., no product was found to contain asbestiform amphibole at a level equal to or greater than 0.5% by weight. "Nonasbestiform Amphibole Detected" means that the product was found by CTFA Method J4-1 to contain only nonasbestiform amphibole at a level equal to approximately 0.5% or greater.

RECEIVED
MAR 9 1978

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3. Destroy your copy of the table.

Your participation in this final important phase of the round robin is appreciated. Thank you very much.

Sincerely,

John P. Schelz, Chairman
CTFA Task Force on
Round Robin Testing of
Consumer Talcum Products

JS/gm
Enclosure

cc (without table): Dr. N. F. Estrin
Vice President-Science, CTFA
Mr. G. Sandland
Bristol-Myers Products

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Exhibit 169

Johnson & Johnson
CONSUMER PRODUCTS WORLDWIDE
SKILLMAN, NJ 08558-9418

June 27, 1995

SUBJECT: CTFA Response to Cancer Prevention Coalition Citizen's Petition

B. Fleming	J. O'Shaughnessy
C. Hammes	K. Schroeher
J. Freedman	M. McTernan
J. Hopkins	N. Matheson
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This forwards a copy of the subject response (submitted to FDA June 9, 1995) for your information and use.

The response was developed by members of the Talc Interested Party Task Force, edited by Dr. Steve Gettings, and reviewed by CTFA legal. As you might guess, we played a significant role in writing, editing, and providing references for the comments. Mike Chudkowski and consultants Bill Ashton and Dr. Al Wehner all contributed a great deal to the final product.

As you will see when reading the response, the petition addressed issues which had been thoroughly examined in January 1994 in a two-day FDA sponsored workshop. The comments we made point out the conclusion of the workshop participants - that cosmetic talc is safe for consumer use.

I will keep you informed of any response we receive. For perspective, the last talc citizen's petition was in FDA review for three years before a response was published.

Donald F. Jones/es

Donald F. Jones

es
Enclosure

cc: W. Ashton
M. Chudkowski
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0037w.dj

COMMENTS

OF

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

IN RESPONSE TO

A CITIZENS PETITION

FILED WITH

THE FOOD AND DRUG ADMINISTRATION

ON NOVEMBER 17, 1994

WHICH WOULD REQUIRE CARCINOGENIC LABELLING

ON ALL

COSMETIC TALC PRODUCTS

FDA Docket No. 94P-0420/CP 1

June 1995

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I. *INTRODUCTION*

The Cosmetic, Toiletry, and Fragrance Association (CTFA)[1] is filing these comments in response to a citizens petition filed by Ms. Jill A. Cashen and Samuel S. Epstein, M.D. on behalf of the Cancer Prevention Coalition ("Petitioner") on November 17, 1994 (FDA Docket No. 94P-0420/CP 1). Petitioner urges the Food and Drug Administration (FDA) to require "cosmetic talcum powder" products to bear labels with warnings such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer". CTFA contends that such labelling is without scientific basis and is unnecessary to protect the health of consumers.

Talc (CAS No. 14807-96-6) comprises pulverized, natural, foliated, hydrous magnesium silicates (Harvey, 1988). As a pure mineral compound, talc is mineralogically defined as hydrous magnesium silicate, with the approximate chemical formula:

$$Mg_3(Si_2O_5)_2(OH)_2$$

The largest commercial uses of talc are in industrial applications such as paint, plastics, paper, ceramics, and construction materials. Talc utilized in direct cosmetic applications accounts for a relatively small percentage of the overall talc market. In 1992, approximately 48,000 tons of talc were used in the United States for cosmetics, pharmaceuticals, and food products (American Westmin, Inc./Luzenac America, unpublished data).

Pharmaceutical tableting and various food applications account for approximately 8% of

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[1]The Cosmetic, Toiletry, and Fragrance Association is the national trade association representing the cosmetic, toiletry and fragrance industry in the United States. CTFA, founded in 1894, represents over 500 companies involved in the personal care products industry. CTFA's active members manufacture and distribute the vast majority of personal care products marketed in the United States. CTFA's associate member companies supply goods and services such as raw materials and packaging to the industry's manufacturers and distributors. The personal care products industry prides itself on a long history of providing safe, reliable products to meet the diverse needs and personal tastes of the American consumer.

direct consumer uses of talc products; the greatest proportion (approximately 92%) is used in cosmetic applications. Used for decades in a wide variety of cosmetic and other applications, talc has proven to be among the safest of all consumer products. The talc industry has adopted stringent quality assurance standards set by the Food Chemical Codex, the United States Pharmacopeia and the Cosmetic, Toiletry and Fragrance Association. The focus of all three specifications is similar in that they place limits on certain extractable elements and other potential chemical contaminants. Only relatively pure talc products are capable of meeting these specifications.

Petitioner contends that labelling of cosmetic talc products is required in order to adequately warn consumers of the risk of ovarian cancer. However, the available literature and the experience of manufacturers provides no evidence that cosmetic talc, when used as intended, presents any health risk to the consumer. All current available safety information on cosmetic talc has been thoroughly reviewed (Wehner, 1994). Moreover, a panel of experts at a workshop organized by FDA and the International Society of Regulatory Toxicology and Pharmacology (ISRTP) convened to review the latest toxicological and epidemiological studies on talc concluded that the "probability of human risk [from talc] is likely non-existent under customary conditions of use "and that "while some weak association between talc exposure and ovarian tumors has been reported, it [is] not sufficient warning for concern" (Carr, 1995).

In summary, there is no evidence to suggest that cosmetic-grade talc is a human carcinogen and in particular there is no convincing evidence to show that frequent talc application in the female genital area may increase the risk of ovarian cancer. Specifically, CTFA will show that:

- the contention that cosmetic-grade talc contains asbestos is unsupportable;

- talc is a rat carcinogen only under conditions which produce particle overload and related chronic toxicity;
- consumer exposure to respirable talc particles is several orders of magnitude lower than exposures which result in rat lung tumors;
- evidence for the role of intrinsic and extrinsic risk factors in the etiology of ovarian epithelial cancer is inconclusive;
- epidemiological evidence supports only a weak statistical association between perineal talc use and ovarian cancer, the significance of which is not considered meaningful; and
- any weak statistical association is unsupported by evidence of a plausible biological mechanism by which talc could cause ovarian cancer.

In short, there is no scientific justification to support the Petitioners contention that cosmetic talc products should bear labels warning that "[t]alcum powder causes cancer in laboratory animals" and that "[f]requent talc application in the female genital area increases the risk of ovarian cancer".

II. THERE IS NO EVIDENCE TO SUGGEST THAT COSMETIC-GRADE TALC IS A HUMAN CARCINOGEN

A. The Contention that Cosmetic-Grade Talc Contains Asbestos is Unsupportable

Petitioner contends that talc used in cosmetic applications contains asbestos. This contention is based on outdated and erroneous evidence which FDA has previously refuted. Petitioner quotes early mineralogical research done by Cralley *et al* (1968) and Rohl *et al* (1976)

which sought to identify asbestos contamination in cosmetic talc. During the early 1970's FDA became concerned that cosmetic talc contained significant amounts of asbestos. However, in response to an earlier Citizens Petition "... FDA considered all analytical results to be of questionable reliability. This assessment proved to be correct because many questions were subsequently raised about results reported in the literature in the early 1970's" (letter from FDA Acting Associate Commissioner for Regulatory Affairs, 1986). In denying the Petition, FDA noted "we find that there is no basis at this time for the agency to conclude that there is a health hazard attributable to asbestos in cosmetic talc" (*Id*).

The historical association between talc and asbestos is an extremely unfortunate one. Precipitated in large part by the use of overly broad definitions of asbestos and nonspecific analytical techniques (Rohl, 1974; Rohl and Langer, 1974; Krause and Ashton, 1978; Parmentier and Gill, 1978), the idea that asbestos is commonly and intimately associated with talc is simply incorrect. As a retrograde mineral, talc may be found in association with chrysotile in serpentinites and other hydrous minerals. However, the geologic conditions under which talc and asbestos form are dissimilar. Many talc-bearing rocks form from ultramafic rocks, the central core of which is composed of serpentinite surrounded, successively, by shells of talc-carbonate rock and talc-bearing steatite (steatite is synonymous with soapstone). Usually a thin wall schistose rock, composed essentially of chlorite, separates the steatite from the country rock. The serpentinite is composed mostly of non-fibrous serpentine minerals (lizardite and antigorite), but small amounts of chrysotile asbestos may also occur within the serpentinite. The talc-carbonate and steatite shells which surround the serpentinite core contain abundant talc but do not contain asbestos. Careful mining procedures enable the serpentinite core to be avoided and thus possible contamination of talc ore with asbestos is obviated. Confirmation of the absence of asbestiform

minerals in the finished talc product is established using x-ray diffraction, optical microscopy and electron microscopy techniques (CTFA, 1990).

B. Talc is a Rat Carcinogen Only Under Conditions Which Produce Particle Overload and Related Chronic Toxicity

Petitioner contends that "[t]alc is a carcinogen, with or without the presence of asbestos-like fibers". In support of this contention, Petitioner relies on the results of studies published by the National Toxicology Program (NTP). Petitioner's reliance is misplaced in that NTP showed talc to be a rat (but not a mouse) carcinogen, and only under circumstances indicative of a secondary mechanism involving particle overload and resultant chronic toxicity. In 1992, NTP reported the results of 2 year inhalation studies designed to determine the effect of talc in experimental animals (NTP, 1993); male and female F344/N rats and B6C3F$_1$ mice were exposed to target aerosol talc concentrations of 0, 6, or 18 mg/m^3 for 6 hours/day, 5 days/week, for 2 years. NTP concluded that:

> *Under the conditions of these inhalation studies, there was some evidence of carcinogenic activity of talc in male F344/N rats based on an increased incidence of benign and malignant pheochromocytomas of the adrenal gland. There was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign and malignant pheochromocytomas of the adrenal gland. There was no evidence of carcinogenic activity of talc in male or female B6C3F$_1$ mice exposed to 6 to 18 mg/m^3.*

Since its publication, the findings of NTP have been criticized by several experts in the field of inhalation toxicology with regard to both study design and conduct. Most notably these

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studies were the subject of a joint ISRTP/FDA scientific workshop held in 1994 (*Talc: Consumer Uses and Health Perspectives;* January 31/February 1, 1994) which discussed the relevance of the NTP findings with regard to consumer exposure and consumer safety. Criticisms of the study made at the workshop may be summarized as follows:

Test Article/Particle Size: The NTP study has questionable relevance with regard to prediction of human risk due to consumer exposure since the talc sample utilized in the NTP study was of a kind which is used in industrial applications, and was not a product that would be used in a cosmetic powder application because of its extreme fineness (Zazenski et al., 1995). The test material used by NTP is an industrial grade product typically used in specialty coatings and high performance polymeric applications. The median particle size of the NTP talc sample was approximately 1.2 microns and had a top size of approximately 10 microns. In contrast, typical commercial loose talc powder has a median particle size of approximately 10 microns and a top size of approximately 45 microns (Zazenski et al., 1995).

Exposure Levels Resulted in Lung Particle Overload: The major criticism of the NTP study is the failure to include exposure levels which did not lead to lung particle overload. The concept of "particle overload" in chronic inhalation studies with highly insoluble particles of relatively low toxicity is now widely accepted (Morrow, 1988). Typically, exposure concentrations are relatively high and result in retained particulate lung burdens which are also high. Such retained lung burdens lead to a sequence of inflammatory responses, altered particle-clearance/retention and altered morphology, leading to chronic disease states including fibrosis and the induction of benign/malignant tumors (see Oberdörster, 1995).

Highly insoluble particles deposited in the lower respiratory tract are removed by two important mechanisms (see Oberdörster, 1995). The mucociliary escalator removes particles

deposited in the conducting airways; particles deposited in the alveolar region are phagocytosed by alveolar macrophages (AM) which then migrate towards the mucociliary escalator and are removed (Schlesinger, 1985, Oberdörster, 1988; Snipes, 1989). When deposition rate in the alveolar region exceeds the AM-medicated clearance rate, alveolar retention halftime is considerably increased (often irreversibly) and results in excessive accumulation of particles in the lung. One further consequence of excessive accumulation is increased translocation of particles to the pulmonary interstitium which eventually results in the induction of pulmonary fibrosis (Adamson et al., 1989; Bowden et al., 1989), activation of macrophages and release of cytokines resulting in increased epithelial cell proliferation (Driscoll et al., 1990).

Based on the actual talc burdens of exposed rats (ie., as measured by NTP), Oberdörster (1995) has estimated that the pulmonary retention halftimes of the retained talc particles range between 250 and 300 days, ie., is markedly longer than the normal retention halftime for highly insoluble particles in rat lungs of ~70 days. Oberdörster has concluded that these results are indicative of lung particle overload. Oberdörster has also shown that the talc-exposed mice exhibited a marked increase in pulmonary retention halftime for talc particles with increasing lung burdens (i.e., a severe retardation of normal AM-mediated particle clearance) compared to a normal retention halftime in mice lungs. In summary, the lung particle clearance was impaired in both rats and mice in the NTP study, resulting in altered accumulation kinetics of talc particles chronically inhaled at concentrations of 6 and 18 mg/m^3. The rat tumor response is thus very likely a secondary effect of the particle overload phenomenon ie., due to altered lung clearance kinetics resulting in excessively high lung burdens leading to chronic inflammatory and cell proliferative processes (Oberdörster, 1995). Conceivably, the difference in tumor response between male and female rats may be merely temporal since hyperplasia and an interstitial fibrosis

was observed in both sexes. Oberdörster attributes the lack of pulmonary tumors in mice to the fact that rat lung tumors associated with a high pulmonary particle load appears to be a very species-specific response to non-fibrous particles (Oberdörster, 1995).

Exposure Levels Exceeded the MTD: The highest dose in carcinogenicity studies is generally designed to be equivalent to the maximum tolerated dose (MTD). Although this principle has become increasingly subject to criticism, high-dose testing at the MTD remains the practice of NTP. In general, the MTD is estimated following a careful analysis of data from appropriate subchronic toxicity tests. The need to consider a broad range of biological information when selecting the MTD has become increasingly clear. For example, data concerning changes in body/ organ weight, clinically significant alterations in hematologic, urinary and clinical chemistry measurements, as well as more definitive toxic, gross or histopathologic endpoints can be used to estimate the MTD.

For chronic inhalation studies with highly insoluble particles of low cytotoxicity, the phenomenon of particle overload and the question of exceeding the MTD are intimately interrelated. Recommendations of a NTP Workshop on Maximal Aerosol Exposure Concentrations in Inhalation Studies (Lewis *et al.*, 1989) included "[the] chronic study should *not* (emphasis supplied) be performed at the highest technologically feasible concentration, three concentrations should be used of which only the highest should show some interference with lung defense mechanisms, i.e., clearance impairment; and the two lower concentrations should show no interference with clearance and particle accumulation". Based on these criteria, the MTD was clearly exceeded in the studies conducted by NTP on talc.

In the NTP study, talc-induced lung tumors were not detected in male rats, female mice or male mice. In rats, the principal toxic lesions associated with inhalation exposure to talc included

chronic granulomatous inflammation, alveolar epithelial hyperplasia, squamous metaplasia and squamous cysts, and interstitial fibrosis of the lung. These lesions were accompanied by impaired pulmonary function. While the talc burden in the lungs of males and females was similar, the degree of chronic toxicity and inflammation was substantially higher in females. In mice, inhalation exposure to talc produced some chronic inflammation. In contrast to rats, alveolar epithelial hyperplasia, squamous metaplasia, and interstitial fibrosis were not observed. Overall, markedly less talc-induced lung toxicity was produced in mice than in rats. In summary, it is apparent that an increase in lung tumors was seen only in the test animals that clearly exhibited the highest degree of chronic lung toxicity, (ie., the female rats exposed to 18 mg/m^3 talc). Similarly, the increased incidence of pheochromocytomas is most likely attributable to the stressful conditions (eg., as a result of physiological, metabolic or endocrine changes) to which the test animals were exposed. In addition, the F344/N rat is known to have a high background incidence of pheochromocytomas (NTP, 1993). The relevance of these responses with regard to extrapolation to humans is thus highly suspect (Goodman, 1995).

The unmistakable conclusion from these observations is that the MTD was exceeded in the female rats exposed to the high dose, and that talc is not expected to cause lung tumors under conditions of exposure that fail to result in marked chronic lung toxicity (Goodman, 1995). In contrast to Petitioner's characterization of the results of the NTP study, clear evidence of carcinogenic activity of talc was seen *only* in female rats (not male or female mice) exposed to the high dose of talc and *only* under circumstances in which there was evidence of particle overload and marked chronic lung toxicity. In summarizing it's assessment of the NTP study, the panel of experts at the ISRTP/FDA workshop *Talc: Consumer Uses and Health Perspectives* characterized the positive results in female F344/N rats as "likely experimental artifact...[a] non-

specific generic response of dust overload of the lungs, and not a reflection of a direct activity of talc. Given the gross differences of rodent and human lungs, the lung clearance capabilities of humans and the possible conditions of customary human exposures, the NTP bioassay results in F344/N rats cannot be considered as relevant predictors of human risk" (Carr, 1995).

C. Consumer Exposure to Respirable Talc Particles is Several Orders of Magnitude Lower Than Exposures Which Result in Rat Lung Tumors

Although Petitioner would require warning labels to the effect that "[t]alcum powder causes cancer in laboratory animals", the implication is that talc exposure constitutes human risk of cancer. Such an implication is unwarranted since consumer exposure to talc is considerably lower than exposures which result in rat lung tumors. Consumers are exposed to talc during the application and use of body powders. In this regard, human exposure occurs principally via the dermal route, but primary concern has focused on exposure via the respiratory tract. Talc miners and millers are exposed to long-term, relatively high concentrations of airborne talc; the results of human cohort studies involving cosmetic grade talc miners and millers thus provide a useful basis against which pulmonary risk to consumers may be estimated (Scansetti et al., 1963; El-Ghawabi et al., 1970; Rubino et al., 1976; Gamble et al., 1982; Wegman et al., 1982; Leophonte et al., 1983; Wergeland et al., 1990). These studies show that a pneumoconiosis (talcosis) risk does exist but only when respirable talc dust levels are significantly greater than worst-case consumer exposures (described below) and exposure is over an extended period of time (several years).

While there may be disagreement over the amount of exposure required to induce pneumoconiosis, such studies suggest that talc poses a low to moderate pulmonary risk in an industrial setting. For example, in a mortality and morbidity study of Italian talc miners and millers, radiographic abnormalities consistent with pneumoconiosis were found among talc

workers after an average duration of exposure for 22 years, with an average respirable dust concentration of approximately 11 mppcf (Rubino, et al., 1976); in contrast, in a study involving French talc workers, no cases of pneumoconiosis at a level of 15 mppcf were reported (Leophonte, et al., 1983). Although it is difficult to reliably convert respirable particle count data (mppcf) into respirable gravimetric data (mg/m^3), such levels typically fall into the 1-2 mg/m3 range (e.g., in a study of Vermont talc miners and millers (Boundy et al., 1979), pneumoconiosis was observed when respirable dust levels ranged from 0.5 to 2.9 mg/m3). Despite the incidence of pneumoconiosis at high industrial exposure levels it is important to note that an excess prevalence of lung cancer in talc mining populations has not been observed (Selevan et al 1979; Leophonte et al., 1983; Wergeland et al., 1990; Rubino et al., 1976).

Electrostatic, Van der Waal's and valance charges present on the particulate surfaces of a dry powder such as talc result in substantial particle-to-particle agglomeration, thereby increasing effective mass, diameter, and settling velocity (Carta et al., 1981; Gajewski, 1990). These factors are important with regard to influencing the respirability of dry particles. Two studies have been conducted to evaluate exposures to respirable particles during application of talc as an adult body powder and as a baby powder (Russell et al., 1979; Aylott, et al., 1979). In both studies, respirable particles ($\leq$ 10 microns) were collected usig a cyclone particle fractionation system operating at an air flow rate of 1.7-1.9 liters/minute. Adult exposure was assessed during normal face/body powdering practices by placing cyclone collection units on shelves at appropriate face height, or by positioning a cyclone attached to a headband near the nose (i.e., in the subjects breathing zone). To evaluate the exposure of babies to talc, sampling units were placed on the changing table near the infants' (or doll's) heads during normal powdering practices (i.e., while changing a diaper). Talc was dispensed using common twist-top, sprinkle-type containers, or in

the case of face powder, powder puffs. Exposure of adults to respirable particles during application of talc ranged from 0.48 to 2.03 mg/m^3, while the exposure to babies ranged from 0.19 to 0.21 mg/m^3. When these numbers are extrapolated to 8-hour time weighted average exposures, they range from <0.001 to 0.005 mg/m^3 (Zazenski et al., 1995). For comparison purposes, the current OSHA/ACGIH permissible industrial exposure limit for talc is 2.0 mg/m^3 as an 8 hour time-weighted average (ACGIH, 1992), i.e., the industrial permissible limit is approximately 350 times greater than the worst case consumer use of cosmetic grade talc.

Based upon the determinations reported in the literature, human exposure to respirable talc particles during normal product use are approximately 2,000-20,000 times lower than those used to expose rats and mice in inhalation studies conducted by the NTP (Zazenski et al., 1995). Although a direct comparison of the dosimetry of inhaled materials between rodents and humans is far from simple (Dahl et al., 1991), such a broad difference in exposure level is quite striking. The incidence of tumors resulting from massive exposures such as those involved in the NTP talc inhalation study are more likely to reflect a particle overloading effect in the experimental animals (Morrow, 1988; Morrow, 1992; Oberdörster, 1988) than any genotoxic effect associated with the test material (Endo-Capron et al., 1993).

As previously noted, the talc sample utilized in the NTP study was not a product that would be used in a cosmetic powder application because of its extreme fineness (SECTION II. B). Further, the NTP talc aerosol was exposed to Kr-85 gamma radiation immediately prior to its introduction into the exposure chambers containing the experimental animals. Use of ionizing radiation was intended to neutralize the electrical charge imparted on the talc particles during aerosolization. Charge neutralization tends to decrease agglomeration and results in deposition of particles in the deep lung of exposed animals. Thus, while selection of an ultra-fine product

combined with procedures designed to maximize particle dispersion may be entirely appropriate from a toxicological perspective, such an artificial environment has questionable relevance with regard to actual human exposure from commercial cosmetic talc products under use conditions.

SECTION II. SUMMARY

The issues raised by Petitioner with regard to asbestos contamination of cosmetic-grade talc have previously been addressed by FDA. In 1986, FDA concluded that there was no health hazard attributable to asbestos in cosmetic talc. Since that time no new evidence has arisen which would suggest a conclusion to the contrary; moreover, appropriate selection of mine site, careful mining procedures and the utilization of modern beneficiation techniques have further safeguarded against asbestos contamination. Accordingly, CTFA believes that FDA's response to the issue of asbestos contamination raised by Petitioner should be no different than its response in 1986.

With regard to Petitioner's assertion that talc is an animal carcinogen, the NTP chronic inhalation study has been subject to severe criticism. The test material used by NTP was characterized by an extremely small particle size and is not characteristic of material used for cosmetic talc applications. Further, the exposure levels chosen by NTP clearly exceeded the MTD for talc and were such that exposure resulted in impairment of lung clearance mechanisms and a condition known as particle overload. Because any highly persistent particulate compound of low cytotoxicity has carcinogenic potential, particularly in rats, when chronically inhaled at such high concentrations, the classification of such particles with respect to pulmonary carcinogenicity must be carefully evaluated. In the absence of any evidence of a toxic or genotoxic effect *per se*, the only reasonable conclusion which may be drawn from the studies conducted by NTP is that the carcinogenic effect of talc is a secondary phenomenon which does

not occur in the absence of chronic toxicity which is itself a result of particle overload.

In summary, the application of the results of the NTP study with regard to human risk assessment are highly questionable. Consumer exposure to respirable talc particles is several orders of magnitude lower than exposures which result in rodent tumors. There is no evidence of chronic toxicity following consumer exposure to talc, thus use of the lung tumor endpoint in female rats as the basis of extrapolation to human risk is inappropriate. Clearly, Petitioner's request that FDA require warnings such as "[t]alcum powder causes cancer in laboratory animals", with it's implicit message that talc may cause human risk of cancer, is both misleading and may cause consumers unnecessary concern. As such, Petitioner's request should be denied.

III. THERE IS NO CONVINCING EVIDENCE TO SUPPORT THE CONTENTION THAT FREQUENT TALC APPLICATION IN THE FEMALE GENITAL AREA MAY INCREASE THE RISK OF OVARIAN CANCER

A. Evidence For The Role Of Either Intrinsic Or Extrinsic Risk Factors In The Etiology Of Ovarian Epithelial Cancer Is Inconclusive

The etiology of human ovarian epithelial cancer is not clearly understood. Ovarian tumors of epithelial origin, which include serous, mucinous, endometrioid, clear cell and undifferentiated adenocarcinomas and the Brenner tumor, are responsible for the majority of ovarian malignancies (Cannistra, 1993; Slotman and Roa, 1988). The purported extrinsic and intrinsic risk factors which contribute to the incidence of epithelial cancer of the ovary have been the subject of numerous reviews (Shoham, 1994; Kelsey et al., 1994; Dietl and Marzusch, 1993; Parazzini et al., 1991; Baylis et al., 1986; Heintz et al., 1985). While a number of scientists have attempted to identify various extrinsic risk factors, including environmental (e.g. tobacco and talc), infectious disease (e.g. mumps, rubella), and dietary intake (e.g. lactose, animal fat, alcohol, caffeine) as

potential etiologic agents, the data are inconclusive. At best, some studies have demonstrated a relationship between dietary factors and the incidence of ovarian epithelial cancer: in particular, an increased risk for ovarian cancer has been reported for women who consume diets which are high in animal fat (Shu et al., 1989; Mori and Miyake, 1988; La Vecchia, et al., 1987) and lactose (Cramer, 1989; Cramer et al., 1989).

Research investigating intrinsic risk factors has provided evidence which suggests that reproductive history and molecular factors are strongly linked to carcinogenesis of the ovarian epithelium. It is well documented that suppression of ovulation, either by pregnancy or by oral contraceptive use, decreases the risk for developing ovarian cancer (McGowan et al., 1979; Wu et al., 1988; Mori et al., 1988; Booth et al., 1989). Ovulation is a physiologic process which is mediated by hormones (gonadotropins) and results in repeated ruptures in the surface epithelia of the ovary. Following ovulation, a repair process takes place whereby there is an increase in epithelial cell mitotic activity. The reduced risk afforded by pregnancy or by oral contraceptive use is postulated to be meditated by the subsequent decrease in circulating gonadotropins and/or the suppression of ovulation (Whittemore, et al., 1992). Evidence supporting the etiologic role of ovulation has been provided by *in vitro* studies demonstrating that the repeated cell division of ovarian surface epithelial cells results in a malignant transformation (Godwin et al., 1993).

Molecular events associated with the initiation of ovarian cancer have recently been reviewed (Berek and Martinez-Maza, 1994; Godwin et al., 1993). Genetic mutations are molecular events which can lead to tumor formation. Studies assessing family history have reported a genetic predisposition to ovarian cancer (Patel and Obrams, 1993; Hartge et al., 1989) which appears to be inherited on an autosomal dominant gene (Slotman and Rao, 1988). Specific loss of a gene at the 6*q* chromosomal loci has been identified in ovarian tumors (Lee et al., 1990);

additionally, genetic alterations on chromosomes 1,3, 14 and 17 have been identified in certain ovarian carcinomas (Daly, 1992). Mutations can result in chromosome alterations and the subsequent inactivation of a particular gene. Studies conducted by Hoffman and colleagues (1993) have demonstrated a reduced expression of a cell adhesion molecule (E-cadherin) in an *in vitro* model of ovarian epithelial carcinogenesis. Genetic alterations can also lead to the overexpression of a gene. Proteins encoding certain chemical messengers (cytokines), such as IL-6 (interleukin 6), M-CSG (macrophage colony stimulating factor) and TNF (tumor necrosis factor) have been found to be increased in epithelial ovarian cancer cells (Malik and Balkwill, 1991).

In summary, the events which lead to development of ovarian epithelial cancer are not clearly understood. A variety of intrinsic and extrinsic risk factors may be involved. However, in light of the fact that cancer is a disease which evolves at the molecular level, it is likely that research investigating the molecular aspects of ovarian cancer may provide important insight how such risk factors relate to incidence. It is significant in this respect that a thorough review of the toxicology of talc reveals no evidence any genotoxicity (Wehner, 1994).

B. Epidemiological Evidence Suggests Only a Weak Statistical Association Between Perineal Talc Use and Ovarian Cancer, the Significance of Which is Not Considered Meaningful

Although several studies on the possible association between perineal talc use and ovarian cancer have been published, any evidence of such an association remains equivocal. At most, the statistical association is weak and in the absence of evidence of a plausible biological mechanism (SECTION III. C) is insufficient to warrant public health concern. There have been seven case-control studies and one cohort study that have been published containing information regarding

the risk of ovarian cancer in women using talc in their perineal region (Cramer et al., 1982; Hartge et al., 1983; Whittemore et al., 1988; Booth et al., 1989; Harlow and Weiss, 1989; Harlow et al., 1992; Rosenblatt et al., 1992; Hankinson et al., 1993). Talc exposure was the primary focus in only four of these studies (Cramer et al., 1982; Hartge et al., 1983; Harlow and Weiss, 1989; Harlow et al., 1992).

Cramer *et al* (1982) investigated whether there is an association between exposure to certain hydrous magnesium silicates (including talc), and the incidence of ovarian cancer. Population-based matched controls were randomly selected, and stratification and logistic regression were used to accommodate confounders. Overall, 42.8% of cases and 28.4% of controls reported exposure to talc, via direct application to the perineum, by dusting sanitary napkins, or both. The unadjusted odds ratio (OR) of ovarian cancer for any perineal exposure as opposed to no perineal exposure was 1.89 (95% CI 1.27-2.82). Adjustment was then made for parity and menopausal status. Women who used talc on both the perineum and sanitary napkin had an adjusted OR of 3.28 (95% CI 1.68-6.42) and for any exposure, 1.61 (95% CI 1.04-2.49). The reduction in risk from 1.89 to 1.61 for perineal talc exposure due to logistic regression is largely unexplained and may be due to residual confounding. No dose-response or duration data were reported. While a major strength of the study is the use of neighborhood controls, the nonparticipation rate among controls was relatively high (260/475=55%).

Hartge *et al* (1983) investigated the association between talc use and the risk of ovarian cancer but reported no significant finding. The cases were women with pathologically confirmed primary epithelial ovarian cancer, while the hospital based controls had non-gynecological conditions (psychiatrically disturbed women, pregnant women, and women with other malignancies were excluded). Controls were frequency matched on age, race and hospital. For

the group of women who did not use talc versus the group of women who did, the unadjusted OR of ovarian cancer was 0.776 (95% CI 0.47-1.20). Although no attempt was made to control for potential confounding variables, this nonsignificant odds ratio was unaffected by adjustment for parity, race and age.

Lifetime consumption of coffee, tobacco and alcohol were the principal exposure factors studied by Whittemore *et al* (1988). Women diagnosed with ovarian cancer in the San Francisco Bay area between 1983-5 provided the cases for this study. Matched controls from two groups, hospital and population, were obtained. The hospital controls were selected from the same hospitals as the cases, whereas the population controls were selected using random digit dialing. All controls were matched to cases on age, race, and having at least one ovary. Logistic regression was used to adjust for confounders. While this study examined other potential risk factors as well as talc exposure in relation to ovarian cancer, the study did not find evidence of an association between genital talc exposure and an increased risk of ovarian cancer. While women who reported regular use of talc on the perineum showed a marginally significant increase in relative risk, no other differences were noted between cases and controls when considering other types of perineal talc exposure either alone or taken in combination. The unadjusted OR of ovarian cancer for any perineal exposure as opposed to no perineal exposure was 1.19 (95% CI 0.85-1.66). Adjusted for parity, the OR was 1.40 (95% CI 0.98-1.99). Other odds ratios also failed to produce significant associations. Several sources of bias were identified, including failure to interview all eligible cases, the potential pitfalls in combining hospital and population controls, confounding by differential talc use among women with characteristics predictive of ovarian cancer and random error in reported talc use tending to attenuate relative risk estimates. The study raises the possibility that a hormonal factor that may place women at a higher risk for the

disease may also promote their use of talc.

Booth *et al* (1989) studied various potential risk factors for ovarian cancer including infertility, oral contraceptive use, parity, age at menopause, and genital talc use. Women with a diagnosis of ovarian cancer and treated at a London cancer hospital were each age matched to two hospital controls at 15 other hospitals. Non-participation rates were not provided, and one hospital providing more than 25% of the cases provided no controls. In addition, cases were generally older and in a higher social class than controls. All odds ratios were adjusted for social class in six categories. Maximum likelihood estimates of the odds ratios with the corresponding 95% confidence intervals were obtained. Logistic regression was used to test for trends. The results were inconclusive since weekly talc use showed a higher OR of ovarian cancer (2.0) than did daily use (1.3), (95% CI 1.3-3.4 and 0.8-1.9, respectively). Furthermore, there was no significant difference between cases and controls who used talc in conjunction with a diaphragm. The unadjusted OR of ovarian cancer with regard to talc use was a statistically nonsignificant 1.29 (95% CI 0.92-1.81). Overall, the study does not support the hypothesis that use of perineal talc increases the risk of ovarian cancer.

Harlow and Weiss (1989) investigated whether application of perineal talc application is associated with an increased risk of serous and mucinous borderline ovarian tumors. Cases (residents of three urban, western Washington state counties diagnosed as having a serious or mucinous borderline ovarian tumor) were identified from the corresponding population-based cancer reporting system. Controls were population-based and located through random digit dialing. Women who reported any perineal use of dusting powders had an adjusted OR of 1.1 (95% CI 0.7-2.1) for borderline ovarian tumor. The adjustment was for age, parity, and use of oral contraceptives but not for other possible confounders. Women using deodorizing powder

with or without baby powder (the only powder reported by women using a second powder) showed an increased risk of borderline tumor development, OR of 2.8 (95% CI 1.1-11.7). The elevated risk of borderline ovarian cancer among women who specifically used deodorizing powders may have been due to chance or applicable only to borderline but not malignant tumors.

Harlow *et al* (1992) investigated whether the use of talc increases the risk for epithelial ovarian cancer. Between July, 1984, and September, 1989, cases were diagnosed with borderline or malignant epithelial ovarian cancer at 10 different Boston metropolitan hospitals. Population controls were age matched and were all Caucasian. The influence of confounders and effect modifiers was assessed through stratification and logistic regression. Overall, 49% of cases and 39% of controls reported exposure to talc, yielding an OR of 1.5 (95% CI 1.0-2.1) for ovarian cancer. Among women with perineal exposure to talc, the risk was significantly elevated in subgroups of women who applied it directly as body powder (OR of 1.7; 95% CI 1.1-2.7). Women with an intact genital tract (and who had at least 10,000 applications while ovulating) showed an OR of 2.8 (95% CI 1.4-5.4). Although this study seemingly suggests a small increased risk of epithelial ovarian cancer due to lifetime use of perineal talc, the association is still not entirely clear. One important potential confounder that was not accounted for in this study was oral contraceptive use. More controls used oral contraceptives than cases, and oral contraceptive use was associated with less reported talc exposure. Thus, use of oral contraceptives is a possible strong confounder that, if properly considered, could eliminate any observed effect.

Rosenblatt *et al* (1992) studied the relationship between "fiber" exposure (Note: these investigators mischaracterize talc as "fiber"; other exposures include asbestos and fiberglass) and epithelial ovarian cancer. Controls, who were hospital-based and free of gynecological and malignant conditions, were matched to cases by age, race and date of diagnostic admission. Due

to the strict inclusion criteria, controls could not be found for each case. Thus although 140 new cases were located and 108 were successfully interviewed, only 77 cases were entered into the study. The OR (adjusted for number of live births) was 1.0 (95% CI 0.2-4.0) for women reporting any genital "fiber" use versus those women who were not so exposed; the unadjusted OR was 0.84 (95% CI 0.27-2.63). An increased risk of ovarian cancer was observed for women who used talc on their sanitary napkins with an OR of 4.79 (95% CI 1.29-17.79). However, among the remaining eight odds ratios, none was statistically significant. While there seems to be an elevated risk of ovarian cancer in women who used talc on sanitary napkins, this finding is not supported by other studies (eg., Harlow *et al.*, (1992) did not report an elevated risk in this category).

The most recent study in which an indirect comparison of ovarian cancer incidence in talc users versus nonusers can be made was reported by Hankinson *et al* (1993). The purpose of this study was to assess whether tubal ligation and hysterectomy affected subsequent risk of ovarian cancer based upon the hypothesis that such procedures could prevent translocarion of talc to the ovaries. In reporting a finding of no association between talc use and an increased risk of ovarian cancer the authors found that tubal ligation was "highly protective in women who reported never using talc". Such a finding tends to discount the talc translocation hypothesis discussed in SECTION III.C, below).

In reviewing evidence of the proposed association of talc exposure and ovarian cancer, the panel of experts at the ISRTP/FDA workshop *Talc: Consumer Uses and Health Perspectives* found that the "epidemiologic data are conflicting and remain equivocal" (Carr, 1995). The panel noted the problems connected with the epidemiology of weak associations and the fact that any properly designed study to determine the association between perineal talc use and ovarian cancer

must account for other possible risk factors. These other factors include (but are not necessarily limited to) age, oral contraceptive use, number of term pregnancies, menopausal status, and other, environmental factors such as smoking status, alcohol and caffeine consumption. Other confounding variables, such as vulvovaginal diseases and obesity may also be causally related to ovarian cancer (Rosenblatt et al., 1992). In such instances (where talc use is associated with such conditions because of the degree of comfort it imparts to those affected), any statistical association between talc use and ovarian cancer may be merely coincidental.

In summary, the results of epidemiological studies are inconsistent and ambiguous. Any reported association between perineal talc use and ovarian cancer is weak and statistically barely significant. The biological significance (and hence public health significance) of any such weak association remains obscure.

C. Any Weak Statistical Association is Unsupported by Evidence of a Plausible Biological Mechanism by Which Talc Could Cause Ovarian Cancer

As previously described (SECTION III. B), several investigators have proposed that, based on weak epidemiological evidence, chronic perineal use of talc, including direct application or application to under garments, sanitary napkins or diaphragms, may increase the risk of ovarian cancer. In order for this to occur, talc particles (which have no inherent locomotive capability) would have to migrate from the perineum to the ovaries of exposed individuals. In order to try to identify such a potential translocation process, several studies have been conducted in various species, including humans. Many of these studies are so fraught with problems as to render the results of such studies ambiguous.

Egli and Newton (1961) have claimed that half an hour following vaginal deposition of carbon black particles, translocation occurred from the vagina to the oviducts in two of three

female patients. The results of this study are subject to considerable doubt since the investigators failed to utilize either solution or filter blanks as negative controls. Wehner *et al* (1985) subsequently conducted a similar study in cynomolgus monkeys and found no difference in the number of carbon black particles in the blanks compared to the oviduct rinse solution.

In a study conducted by De Boer (1972), carbon black particles were deposited in the uterus, cervical canal, or vagina of over 100 patients prior to abdominal surgery. Subsequent evaluation showed that when deposited in the uterus, carbon black particles translocated to the oviducts and beyond; particles placed in the cervical canal migrated to a lesser extent. Translocation from the vagina occurred in only 2 of 37 patients: in both cases the patients were placed in the Trendelenburg position, resulting in a negative intra-abdominal pressure. Such negative pressure was considered by the investigator to have been sufficient to draw up material from the vagina, especially when the patient was anesthetized and had a relaxed cervix.

Translocation studies have also been performed in laboratory animals. Henderson *et al* (1986) injected a suspension of talc particles into the cervical canal of 8 female ex-breeder Sprague-Dawley rats. A group of four animals was sacrificed 5 days later, while the remaining 4 animals received additional installations 6 and 15 days following initial treatment. Two of these animals were further administered the talc suspension at 22 and 30 days; six other animals received intra-vaginal injections of talc particles. Subsequent evaluation showed that all animals receiving intrauterine deposition of talc (and 2 of 6 receiving intra-vaginal administration) resulted in the detection of talc particles in the ovaries. Wehner (1994) has suggested that the hydrostatic pressure of the saline solution enhanced the potential for translocation under such conditions. In contrast Phillips *et al* (1978) found no radiolabel in the ovaries of rabbits given either single or multiple intra-vaginal doses of ^{3}H-labelled talc.

An attempt to quantify the amount of talc supposedly found in human ovarian tissue (normal ovaries, cystic ovaries, and ovarian adenocarcinomas) has been made by Henderson *et al* (1979). According to these investigators, normal ovarian tissue contained up to 55,100 particles of talc per gram of wet weight of tissue, while cystic ovaries and ovarian adenocarcinomas contained up to 24,300 particles. However, because talc is ubiquitous, especially in a laboratory or surgical setting, it is difficult to determine if the talc observed in such clinical specimens is due to a specific exposure or contamination. In order to specifically and clearly evaluate the potential for translocation of talc from the vagina to the ovaries, Wehner *et al.* (1986) used neutron-activated talc with subsequent gamma-ray analysis in order to rule out contamination. These investigators used cynomolgus monkeys since the physiological and anatomical characteristics of this species resembles the human female more closely than any other readily available laboratory animal (cynomolgus monkeys have an estrous cycle of 28 days and menstruation lasts 2-7 days). Neutron-activated talc was deposited in the vagina for 30 consecutive working days (45 calendar days); thus exposure occurred through at least one menstrual cycle. Oxytocin was administered once per week during the study to induce the type of uterine contractions thought to occur during coitus and which may enhance the translocation process. The vagina/cervix, uterus, oviduct, ovaries and peritoneal lavage fluid of exposed animals were subsequently examined. Talc was observed only at the site of administration (vagina/cervix) and none was found in the ovaries.

In the carcinogenicity studies conducted by NTP (see SECTION II. B) male and female F344/N rats and B6C3F1 mice were exposed to target aerosol concentrations of 0,6 and 18 mg/m^3 talc for 6 hours daily, 5 days per week, for two years. Such conditions resulted in exposure via inhalation, oral and dermal (including perineal) routes. Initial tissue examination found no exposure-related lesions in either rat or mouse ovaries (NTP, 1993). Subsequent

histological examination of the ovaries and ovarian bursa from rats confirmed this finding and demonstrated no material consistent with the appearance of talc in any animals from any group (Boorman and Seely, 1995).

In summary, available histologic and physiologic studies provide no concrete basis to conclude that talc can plausibly migrate to the ovaries from the perineal region. In the absence of such biological evidence, conflicting and equivocal evidence of a weak statistical association between perineal talc use and ovarian cancer is insufficient to "raise concern at level sufficient to warrant regulatory or public health measures" (Carr, 1995).

SECTION III. SUMMARY

Although several possible intrinsic and extrinsic risk factors have been suggested, the etiology of ovarian epithelial cancer is presently unknown. Critics of the supposed association between talc and ovarian cancer highlight the reported weak associations and the numerous confounding variables (e.g., interview case/control comparisons, failure to adequately address key independent risk factors, etc.) which characterize much of the epidemiological research in this area. Further, experimental studies in which neutron-activated talc was repeatedly introduced into the vagina of cynomolgus monkeys, failed to demonstrate translocation to the cervix, uterus or ovaries. The results of these studies in monkeys suggest that any increased risk of ovarian cancer following perineal exposure to talc is biologically implausible. While deserving of further study, a causal association between perineal talc application and ovarian cancer appears improbable at this time.

IV. CONCLUSIONS

In January 31- February 1, 1994, a workshop organized by FDA and the International Society of Regulatory Toxicology and Pharmacology (ISRTP) was convened to provide a forum for an updated discussion of the origins, manufacture, characterization, toxicology and epidemiology of talc.[2] The principal focus of the meeting was on the latest toxicologic and epidemiologic studies and their significance with regard to the safe uses of talc in consumer products.

At the conclusion of the workshop, a panel of independent experts were able to reach a series of unanimous conclusions. With regard to the NTP talc bioassay in rodents, the panel found that "because of the extreme doses and the unrealistic particle sizes of the talc employed, because of the negative results in mice and male rats, because of the lack of tumor excess at the low doses, and because of the clear biochemical and cytological markers of excessive toxicity in female rats, the positive talc bioassay results in female F344/N rats are likely the result of experimental artifact and a non-specific, generic response of dust overload of the lungs, and not a reflection of a direct activity of talc. Given the gross differences of rodent and human lungs, the lung clearance capabilities of humans and the possible conditions of customary human exposures, the NTP bioassay results in F344/N female rats cannot be considered as relevant predictors of human risk" (Carr, 1995).

With regard to the proposed association of talc exposure and ovarian cancer, the panel found that "epidemiologic data are conflicting and remain equivocal". "Diet, parity, contraceptive use, ovulatory frequency, familial predisposition, age to menarche and menopause amongst other factors [are] associat[ed] strongly (and plausibly) with ovarian cancer incidence" (Carr, 1995).

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[2]These conclusions are in large part based upon an Executive Summary which prefaced a series of papers published as the proceedings of the FDA/ISRTP Conference, *Talc: Consumer Uses and Health Perspectives* (Carr, 1995).

These possible confounders, as well as control selection biases, etc., interviewer and interviewee biases, as well as other factors, may well explain the conflicting results that have appeared in the literature. In summary "...epidemiologic studies have provided weak and conflicting risk signals for [the] association [between talc use and ovarian cancer], and it is unlikely that further studies may prove adequate to raise concern at a level sufficient to warrant regulatory or public health measures " (Carr, 1995).

In conclusion, there is no basis to Petitioner's request that cosmetic talc products should bear warning labels to the effect that talcum powder causes cancer in laboratory animals or the "[F] requent talc application in the female genital area increases the risk of ovarian cancer". When used as intended, talc presents no health risk to the consumer. Accordingly Petitioner's request for warning labels on talc-containing cosmetic products should be denied.

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